OVERVIEW

Becoming a Multinational Corporation ("MNC")

We are committed to advancing breakthrough innovation to develop oncology therapeutics with breakthrough efficacy and bringing them to patients worldwide. In 2014, we established SystImmune, Inc. ("**SystImmune**") in Seattle, the United States, to expand our presence in the global biotechnology ecosystem and spearhead "0-to-1" innovation. Iza-bren, our first-in-class epidermal growth factor receptor ("**EGFR**") × human epidermal growth factor receptor 3 ("**HER3**") bispecific antibody-drug conjugate ("**ADC**"), is a flagship achievement arising from these efforts. In December 2023, we entered into a global strategic license and collaboration agreement for iza-bren with Bristol-Myers Squibb Company ("**BMS**") valued at up to US$8.4 billion, including an US$800 million upfront payment. We believe iza-bren has the potential to become a super-blockbuster drug. Pioneering the bispecific ADC field, it is the world's first and, to date, only approved bispecific ADC, ushering in a new era of bispecific ADC therapies. Iza-bren is also the only EGFR × HER3 bispecific ADC to have entered registrational stage globally. Since its clinical progress was first reported, bispecific ADCs have attracted increasing industry attention and development activity globally, reinforcing our position at the forefront of this field.

The development of iza-bren reflects the systematic capabilities underlying our broader innovative drug pipeline, rather than an isolated product success. Guided by our longstanding "science-based, frontier-transcending, data-driven" philosophy of R&D innovation, we have, through more than a decade of rigorous scientific research, established a comprehensive R&D structure and technology platform capable of continuously identifying and developing globally disruptive innovative drugs. As of the Latest Practicable Date, our innovative drug pipeline featured 15 clinical-stage drug candidates, five of which were undergoing clinical development outside China as of the same date. We are focused on the oncology therapeutic area and have strategically deployed three cutting-edge technology tracks — ADCs, antibody-radionuclide conjugates ("**ARCs**") and multi-specific T-cell engagers ("**TCEs**"). ADCs and ARCs enable precise tumor targeting and large-scale tumor cell killing, while TCEs induce T-cell activation, proliferation and differentiation to achieve systemic tumor identification and elimination. We believe our therapeutic philosophy of "large-scale tumor killing + precision targeting" has the potential to reshape the future landscape of cancer treatment. Through the synergistic interplay of ADC, ARC and TCE therapies, we aim to progressively transform malignant tumors into chronic, manageable diseases, thereby extending patients' life expectancy and improving quality of life and, ultimately, enabling long-term survival with cancer through patients' natural lifespan.

Our strategic goal is to become a fully-fledged, globally competitive MNC, thereby enabling us to bring a growing portfolio of innovative therapeutics with the potential to deliver breakthrough efficacy to patients worldwide. We already hold an "entry ticket" to achieve this goal — the super-blockbuster drug, iza-bren — and have largely assembled the core capabilities required to operate as an MNC (namely research and discovery, clinical development, manufacturing and supply, and commercialization, all on a global scale).

Global innovation. We pursue a strategy that combines internally generated "0-to-1" innovation with the integration of externally sourced "0-to-1" innovation. With respect to internal innovation, we operate R&D centers in both the United States and China, namely the SystImmune R&D center in Seattle, and the Baili Pharm R&D center and Baili-Bio R&D center in Chengdu, Sichuan. Through close, efficient collaboration across these centers, we drive the entire innovation continuum — from "0-to-1" breakthroughs that generate novel therapeutic concepts to "1-to-N" acceleration of clinical translation and development — enabling us to sustain our leadership in both innovation and efficiency in global drug development. Our internal innovation capabilities and accumulated scientific know-how and industry insights also enable us to identify, acquire or in-license complementary external assets and integrate them into our technology platforms and pipeline, further strengthening our overall R&D capabilities and innovation potential.

Global clinical development. We have assembled a clinical development team of over 1,000 professionals in China and overseas, including more than 100 members outside China, and are capable of independently operationalizing clinical studies from Phase I to Phase III. We are currently advancing more than 100 clinical trials globally, including three global pivotal registrational trials conducted jointly with BMS for iza-bren and our first independently initiated global Phase III trial evaluating BL-M14D1, our proprietary delta-like ligand 3 ("**DLL3**")-targeted ADC. The initiation of BL-M14D1's global Phase III trial represents a landmark achievement demonstrating our global clinical development capability. We expect to have initiated a total of eight global Phase III trials by the first quarter of 2027. According to CIC, we are one of the few Chinese pharmaceutical companies with the capability to independently sponsor and conduct global Phase III clinical trials.

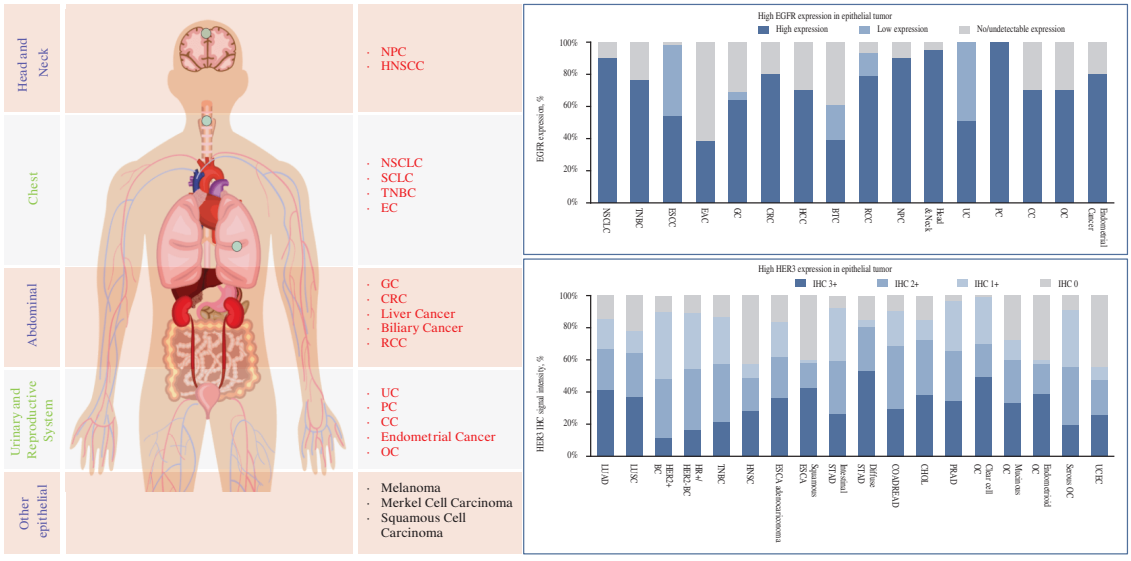
Global manufacturing and supply. We have established a fully integrated manufacturing system spanning the entire value chain. Supported by advanced manufacturing infrastructure and capabilities, this system can meet the supply requirements of global clinical programs while ensuring scalable commercial production of our marketed products. We will continue to expand our manufacturing and supply capabilities to further support the clinical development and subsequent large-scale commercialization of our innovative pipeline products.

Global commercialization. The year 2026 marks our entry into innovative-drug commercialization, with a Core Product, iza-bren, approved for marketing in June 2026. Leveraging our long-standing presence and experience in China's pharmaceutical market, we have established a commercialization team with deep expertise in oncology to support rapid market access and effective market penetration following product launch. With iza-bren expected to receive approvals in overseas markets in the coming years, we will round out our global commercialization capabilities, supporting the commercialization of iza-bren and laying a foundation for the global launch of additional assets from our pipeline.

Our Core Product: Iza-bren, a First-in-Class, New Concept EGFR × HER3 Bispecific ADC

Iza-bren (izalontamab brengitecan, 宜泽康®) is a first-in-class, new-concept and, to date, the only approved bispecific ADC drug globally. It is also the only EGFR × HER3 bispecific ADC to have entered registrational stage globally, underscoring its substantial global clinical value and market potential. As of the Latest Practicable Date, iza-bren had received approvals from the NMPA through the Priority Review Programs for the treatment of adult patients with recurrent or metastatic nasopharyngeal carcinoma ("**NPC**") who had failed at least two prior lines of systemic chemotherapy and treatment with PD-1/PD-L1 inhibitor therapy and for the treatment of adult patients with recurrent or metastatic esophageal squamous cell carcinoma ("**ESCC**") who had failed at least two prior lines of systemic therapy. These approvals provide new treatment options and may reshape the standard of care for the relevant patient population and mark the entry of bispecific ADC therapy into the later-line treatment paradigm for NPC and second-line treatment for ESCC. In addition, iza-bren's new drug application ("**NDA**") for locally advanced or metastatic triple-negative breast cancer ("**TNBC**") had been accepted by the NMPA as of the Latest Practicable Date. These regulatory milestones mark iza-bren's transition from clinical development to commercialization and demonstrate continued progress in realizing its potential value across multiple indications.

EGFR and HER3 are broadly and highly expressed across a wide range of epithelial tumors. Leveraging its bispecific structure, iza-bren is designed to broadly target multiple solid tumors and achieve greater enrichment within tumor tissues, thereby enhancing tumor-killing activity while reducing on-target off-tumor toxicity. Its differentiated design provides the biological foundation for the broad clinical development of iza-bren across multiple tumor types, patient populations and treatment settings. The figures below illustrate major tumor types studied in clinical trials with iza-bren (highlighted in red in the left panel), and various epithelial tumors that exhibit high expression of EGFR and HER3 (shown in the right panel):



Sources: Company data, CIC, PLoS One, Frontiers in Oncology, Expert Review of Anticancer Therapy, British Journal of Cancer, Cancer Res Clinic, Radiation Oncology, Oncology Letters, OncoTargets and Therapy, Nature Cell Biology, World Journal of Gastroenterology, Journal of Pathology, Microbiology and Immunology

Since the initiation of its first-in-human Phase I clinical trial in November 2021, iza-bren has been evaluated in more than 45 clinical trials in China and overseas, with cumulative enrollment exceeding 8,500 patients across over 10 tumor types. Iza-bren has demonstrated encouraging efficacy signals and an overall manageable safety profile across these tumor types, supporting its potential to become a pan-tumor backbone therapy. For example, iza-bren has generated one of the most promising clinical data reported to date in both first-line and later-line settings for non-small cell lung cancer ("**NSCLC**") and small cell lung cancer ("**SCLC**"), according to CIC. Its high response rates, prolonged progression-free survival ("**PFS**"), and encouraging overall survival ("**OS**") signals indicate that iza-bren has the potential to become an important ADC therapy offering both broad applicability and meaningful clinical differentiation.

Durable core patent protection supporting long-term commercialization. The core patent portfolio covering iza-bren is expected to provide protection through November 2042, potentially offering a substantial period of patent exclusivity to support its long-term commercialization in global markets and sustained value realization through indication expansion, global registration, commercial ramp-up and lifecycle management.

Expansive global clinical program. As of the Latest Practicable Date, iza-bren was being evaluated in over 45 clinical trials in China and overseas, comprising (i) 14 Phase III trials in China three of which supported advanced regulatory milestones — the NMPA's conditional approval for NPC, approval for ESCC and acceptance for filing of the NDA for TNBC; (ii) three global pivotal Phase II/III registrational trials; (iii) two additional Phase II/III registrational trials in China; (iv) 21 Phase II trials; and (v) six early-stage trials. In addition, a global Phase III clinical trial for EGFRmut NSCLC is expected to be initiated in September 2026. These trials span first-line, later-line, maintenance and perioperative settings, covering more than 10 major solid tumor types — including lung, breast, gastrointestinal, head and neck, gynecologic and genitourinary cancers — both as monotherapy and in combination regimens.

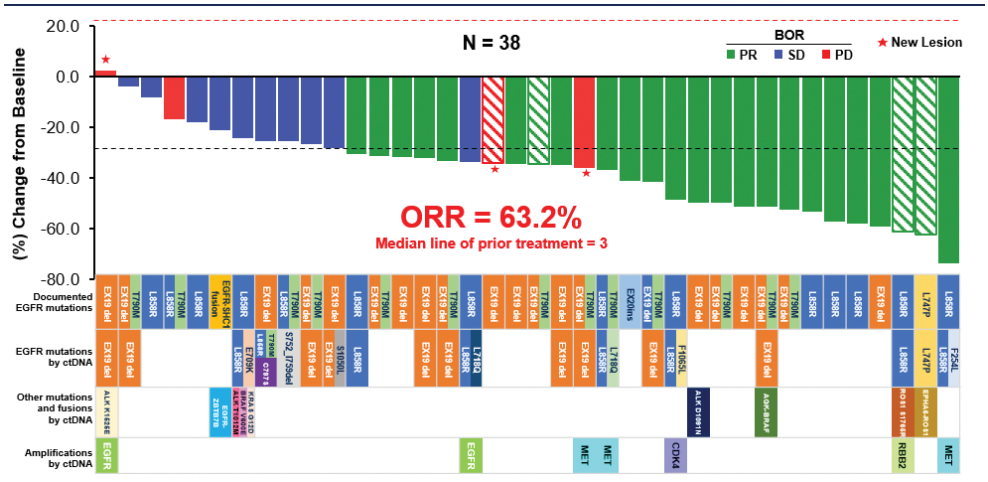
In later-line monotherapy settings, iza-bren has achieved meaningful regulatory progress: two NDAs have been approved for the treatment of NPC and ESCC, and one additional NDA has been accepted for TNBC. We are also advancing iza-bren into earlier-line combination settings through immune-checkpoint-inhibitor-based ("**ICI**") and tyrosine kinase inhibitor ("**TKI**")-based regimens

across over 20 trials. As of the Latest Practicable Date, iza-bren had received breakthrough therapy designations for a total of eight indications, comprising seven indications under the CDE's breakthrough therapy designation program and one indication under the FDA's breakthrough therapy designation.

Next-generation backbone cancer therapy and super-blockbuster potential. Iza-bren's broad clinical validation across treatment settings and tumor types positions it to potentially become the next backbone cancer therapy. In tumors where PD-(L)1 plus chemotherapy is currently first-line standard of care, iza-bren may replace or reduce reliance on the chemotherapy component, offering a potentially better-tolerated regimen. In tumors where first-line treatment is primarily TKI-based, iza-bren is being evaluated in combination with TKIs to explore new treatment paradigms. Its development also extends into earlier-stage disease, including perioperative settings, which represent significant additional market opportunities. If successfully validated across these indications, iza-bren could achieve the broad applicability required to become a super-blockbuster drug — a transformative therapy with global revenue potential of tens of billion.

Clinical results presented at global oncology congresses. As a first-in-class therapy, iza-bren's clinical data have been showcased at leading international oncology congresses — including the American Society of Clinical Oncology ("**ASCO**"), the European Society for Medical Oncology ("**ESMO**"), the World Conference on Lung Cancer ("**WCLC**"), the European Lung Cancer Congress ("**ELCC**") and the San Antonio Breast Cancer Symposium ("**SABCS**") — and published in top-tier peer-reviewed journals such as *The Lancet Oncology* and *Nature Medicine*, demonstrating promising efficacy signals and a favorable safety profile across multiple tumor types.

2023 ASCO — EGFRmut NSCLC (Phase I): At the 2023 ASCO annual meeting, we were invited to give an oral presentation at the session of *Developmental Therapeutics-Molecularly Targeted Agents and Tumor Biology*. The presentation, delivered to over 6,000 attendees including oncology clinical experts and pharmaceutical research scientists, announced first-in-human Phase I data showing an objective response rate ("**ORR**") of 63.2% and disease control rate ("**DCR**") of 89.5% in EGFRmut NSCLC patients. Following this presentation, several top global pharmaceutical companies approached us for partnership discussions, ultimately leading to the BMS collaboration. The chart below shows iza-bren's clinical data in EGFRmut NSCLC we presented at the 2023 ASCO annual meeting. The updated data was published in July 2024 in the globally renowned academic journal, *The Lancet Oncology*.



Source: Our Company's presentation at the oral abstract session during the 2023 ASCO annual meeting, data cut-off date as of March 13, 2023

2025 WCLC — EGFRmut NSCLC (first-line and second-line): At the 2025 WCLC, two iza-bren studies for the treatment of NSCLC were selected for the official press program and presented as oral presentations. The presentations featured breakthrough data from both first-line and later-line settings:

- *First-line:* Iza-bren plus osimertinib achieved a 100% ORR and 100% DCR — the first and only cancer therapy worldwide to achieve 100% ORR in solid tumors. At 12.5 months median follow-up, the 12-month PFS rate was 92.1% and OS rate was 94.8%, the highest ever reported for first-line NSCLC therapy. These results highlight the potential of iza-bren in combination with osimertinib to redefine the first-line treatment standard for EGFRmut NSCLC.

- *Second-line:* Iza-bren monotherapy in post-TKI, chemotherapy-naïve patients achieved median progression-free survival ("**mPFS**") of 12.5 months and 18-month OS rate of 69.2% — the longest mPFS reported for a monotherapy in second-line EGFRmut NSCLC. These results indicate that earlier use of iza-bren following EGFR-TKI therapy may deliver meaningful survival benefit and offer a potential new approach to addressing EGFR-TKI resistance.

2025 ESMO — NPC (Phase III, first approval): Our Phase III study (NCT06118333), the world's first confirmatory randomized controlled Phase III study in post-line treatment for NPC, was selected as a Late-Breaking Abstract, the highest honor at this conference. Iza-bren demonstrated statistically significant improvements over chemotherapy: ORR 54.6% vs. 27.0%, DCR 82.4% vs. 69.6%, median duration of response ("**mDoR**") 8.5 vs. 4.8 months, and mPFS 8.38 vs. 4.34 months. These results directly supported approval of iza-bren's first indication and advanced the treatment of later-line NPC from conventional chemotherapy into the era of bispecific ADC therapy.

At 2025 ESMO, we also released the first multicenter international solid tumor data from the global Phase Ib trial, demonstrating a confirmed ORR of 55.0% and mPFS of 5.4 months in heavily pretreated patients, with particularly compelling signals in lung and breast cancers. Together with the clinical data observed in Chinese patients with advanced solid tumors, these results further demonstrate iza-bren's broad anti-tumor potential across diverse patient populations and tumor types and highlight its promising profile as a versatile therapeutic agent.

2026 ELCC — ES-SCLC (first-line combination): At the 2026 ELCC, we presented Phase II data for iza-bren plus serplulimab as first-line therapy for ES-SCLC — the world's first study evaluating an ADC plus PD-1 inhibitor in this setting. SCLC is an aggressive subtype of lung cancer characterized by rapid progression, high recurrence rates and poor prognosis. Platinum-based chemotherapy combined with immunotherapy has long been the principal first-line treatment for ES-SCLC. However, a substantial unmet clinical need remains for treatments that can provide more durable disease control and improved survival outcomes. In this Phase II study, iza-bren in combination with serplulimab demonstrated encouraging anti-tumor activity and a manageable safety profile, with an ORR of 88.3%, a confirmed objective response rate ("**cORR**") of 77.9%, an mPFS of 8.2 months and a 12-month OS rate of 80.8% (85.7% in the recommended dose cohort). These results suggest that iza-bren in combination with immunotherapy has the potential to help address the plateau in clinical benefit observed with existing chemo-immunotherapy regimens, providing a clinical foundation for advancing to a confirmatory Phase III trial and exploring a new first-line treatment paradigm for SCLC.

2026 ASCO — TNBC and ESCC (Phase III): At the 2026 ASCO Annual Meeting, we presented positive Phase III data in two indications:

- *TNBC:* PANKU-Breast02 is the world's first Phase III study of a bispecific ADC to report positive results for the dual primary endpoints of PFS and OS in TNBC, and the results were selected as a Late-Breaking Abstract. TNBC is an aggressive subtype of BC characterized by poor prognosis and limited treatment options. At a median follow-up of

11.0 months, iza-bren demonstrated statistically significant improvements over chemotherapy in both OS (median overall survival ("**mOS**") 15.9 vs. 12.5 months; HR=0.60, 40% reduction in death risk) and PFS (mPFS 8.5 vs. 3.1 months; HR=0.29, 71% reduction in progression/death risk), with a manageable safety profile (1.9% discontinuation rate, 1.4% interstitial lung disease ("**ILD**") incidence, no Grade 3 or above ILD events). These data demonstrate that iza-bren may offer a new therapeutic option with survival benefit and a manageable safety profile for patients with previously treated advanced TNBC, with the potential to reshape the second-line and later treatment landscape and provide a clinical foundation for further exploration in earlier-line settings. The NDA was accepted by CDE in June 2026.

- *ESCC:* PANKU-Esophagus01 is the world's first Phase III trial of a bispecific ADC in esophageal cancer ("**EC**") to report positive results for both PFS and OS, and the results were selected for oral presentation. In patients with recurrent or metastatic ESCC who progressed after first-line immunotherapy plus platinum-based chemotherapy, subsequent treatment options remain limited and long-term survival outcomes remain suboptimal. Iza-bren achieved significant improvements over chemotherapy in OS (mOS 9.8 vs. 7.2 months; HR=0.64, 36% reduction in death risk) and PFS (mPFS 4.2 vs. 2.0 months; HR=0.50, 50% reduction in progression/death risk), with ORR nearly three times that of chemotherapy (35.3% vs. 13.1%). Iza-bren demonstrated a manageable safety profile with no new safety signals observed. These data indicate that iza-bren has the potential to address an important gap in the second-line treatment landscape for ESCC. The NDA was approved by the NMPA in July 2026.

Collaboration with MNC. On December 11, 2023, we reached a global strategic license and collaboration agreement with BMS. Under the agreement, four joint committees have been established to govern and coordinate the collaboration. BMS and SystImmune will develop iza-bren in the United States in accordance with the global development plan and budget overseen by the joint steering committee and joint development committee. Commercialization of iza-bren in the United States will be conducted pursuant to a commercialization plan and budget jointly developed and finalized by BMS and SystImmune through the joint steering committee and joint commercialization committee. We are exclusively responsible for the development, commercialization, and manufacturing of iza-bren in Chinese Mainland, and will be responsible for manufacturing some of the drug supply for use outside of Chinese Mainland. BMS has an exclusive license for iza-bren in the rest of the world. This collaboration is expected to generate substantial global revenues for us, while also allowing us to extend our biopharmaceutical capabilities beyond early-stage drug discovery and development into global clinical development and commercialization. As of the Latest Practicable Date, we had received the upfront payment of US$800 million and the first clinical trial milestone of US$250 million. We expect to trigger the second clinical trial milestone in the fourth quarter of 2026. See "— License and Collaboration Agreement with Bristol-Myers Squibb Company" for details.

Our Core Product: T-Bren, a HER2 ADC with Best-in-Class Potential to Reshape Treatment Paradigm for Multiple HER2-Expressing Solid Tumors

T-Bren (trastuzumab brengitecan) is our internally developed innovative human epidermal growth factor receptor 2 ("**HER2**")-targeting ADC candidate with best-in-class potential. T-Bren is the second Core Product generated from our high internalizing receptor-targeted antibody-drug conjugate ("**HIRE-ADC**") platform to enter Phase III clinical development, demonstrating the strength of our mature and systematic innovation engine. T-Bren uses our proprietary, globally patented Topoisomerase I ("**Topo1**") inhibitor payload (Ed-04) and a cleavable, highly stable linker. Designed to improve hydrophilicity and reduce aggregation, it has demonstrated stronger antitumor activity than certain marketed HER2 ADCs in various cell line-derived xenograft ("**CDX**") tumor models, with a favorable safety profile. As a next-generation candidate in the HER2 ADC industry, T-Bren has validated its broad development potential in multiple HER2-expressing or HER2-driven solid tumors, including breast cancer ("**BC**"), gastric cancer/gastroesophageal junction adenocarcinoma ("**GC/GEJ**"), lung cancer and ovarian cancer ("**OC**").

As of the Latest Practicable Date, T-Bren was being evaluated in 18 clinical trials in China and overseas, including eight Phase III trials, one Phase II/III registrational trial, three Phase II trials, three Phase I/II trials and three Phase I trials. As of the Latest Practicable Date, one T-Bren indication had been included by the CDE in the breakthrough therapy designation program.

Clinical validation across tumor types. T-Bren has demonstrated positive efficacy and a favorable safety profile across multiple HER2-expressing and HER2-driven solid tumors, with data presented at leading international conferences including ASCO, ESMO and SABCS.

2025 ESMO/ESMO Asia — GC/GEJ and NSCLC. In previously treated HER2+ advanced GC/GEJ, T-Bren demonstrated positive antitumor activity: ORR 55.3%, cORR 47.4%, DCR 92.1%, mPFS 8.4 months; mOS not yet reached. In previously treated HER2-mutant NSCLC, T-Bren achieved cORR 56.9%, with mPFS not yet reached and six-month PFS rate of 88.7%. These data support T-Bren's broad development potential as a next-generation HER2 ADC.

2026 ASCO — OC and BC. At the 2026 ASCO Annual Meeting, we presented Phase II data for T-Bren in two indications, further demonstrating its best-in-class potential:

- *OC:* T-Bren monotherapy data in platinum-resistant recurrent ovarian cancer ("**PROC**") were selected for oral presentation. In pooled analysis of two Phase II studies, T-Bren achieved a cORR of 52.5%, mPFS not reached and a nine-month PFS rate of 54.7% in PROC patients with HER2 expression, with a favorable safety profile (only one Grade 1 ILD case). These data further demonstrate T-Bren's best-in-class potential and support its continued late-stage development in HER2-expressing PROC.

- *BC:* In a Phase II study of T-Bren plus pertuzumab as first-line treatment for HER2+ unresectable locally advanced or metastatic BC, T-Bren achieved one-year PFS rate of 90.8%, one-year OS rate of 95% and cORR of 87.5%, with no treatment-related ILD events. A registrational Phase III study comparing T-Bren plus pertuzumab with docetaxel plus trastuzumab and pertuzumab as first-line therapy is ongoing, the results of which may provide a new potential treatment option for this patient population.

World-Leading Innovative ADC Drug Development Platform: HIRE-ADC

Iza-bren's development exemplifies the systematic outcome of our sustained investment in innovative ADC research over the past decade. We have established the HIRE-ADC platform, a fully integrated, end-to-end platform spanning the key stages of ADC discovery, development and manufacturing, including ADC design, antibody discovery and engineering, payload development, linker and conjugation technologies, efficacy and safety evaluation, process scale-up and commercial-scale manufacturing. This platform has accrued a large volume of foundational research data, enabling the continuous iteration of our innovative ADC technologies and supporting the ongoing development of our innovative drug portfolio.

The HIRE-ADC platform has supported iza-bren's regulatory approval and clinical development, and provides the technological foundation for other ADC candidates including T-Bren, BL-M14D1, BL-M05D1, BL-M11D1, BL-B16D1, BL-M08D1, BL-M09D1 and BL-M24D1. Specifically, BL-M14D1, a DLL3-directed ADC, has advanced into a global Phase III trial in combination with atezolizumab as first-line treatment for extensive-stage small cell lung cancer ("**ES-SCLC**") — our first independently initiated global Phase III trial. BL-M05D1, a Claudin 18.2-directed ADC, has advanced into a Phase III registrational trial for advanced GC/GEJ. These assets demonstrate the platform's repeatable productivity across differentiated targets and global registrational programs. Key capabilities of the HIRE-ADC platform are outlined below.

Antibody discovery and engineering. We have established the "Specificity Enhancement Bispecific Antibody" platform, or SEBA platform, which enables the development of antibody molecules with enhanced tumor selectivity and enrichment features, including SI-B001 (izalontamab), the EGFR × HER3 bispecific antibody used in iza-bren.

Payload development. Our multi-mechanism payload platform addresses tumor heterogeneity and enables large-scale, high-efficiency tumor cell killing. It has generated Ed-04, our proprietary Topo1 inhibitor payload used in iza-bren and T-Bren, as well as next-generation payloads applied to clinical-stage candidates BL-B16D1 and BL-M24D1.

Linker and conjugation technologies. Our proprietary linker and conjugation technologies enable stable conjugation with varying drug-to-antibody ("**DAR**") ratios, supporting both traditional non-specific and precise site-specific conjugation approaches. This flexibility allows us to tailor ADC design to different targets, antibody structures, payloads and intended indications.

World-Leading Innovative Multi-Specific Antibody Platform: GNC

Our proprietary GNC platform is a fully self-developed multi-specific antibody development platform. The platform is designed to generate multi-specific antibodies with symmetrical or asymmetrical architectures that can simultaneously engage multiple distinct antigens. Through the coordinated interaction of multiple tumor- and immune-related protein domains, GNC molecules are designed to synergistically modulate multiple immune mechanisms, thereby "guiding," "navigating" and "controlling" immune cells to induce targeted, activated immune responses against tumor or other pathogenic cells.

GNC-038, a representative drug candidate generated from our GNC platform, is an innovative recombinant humanized tetra-specific antibody targeting cluster of differentiation 3 ("**CD3**"), 4-1BB, PD-L1 and cluster of differentiation 19 ("**CD19**"). Its multi-target design is intended to coordinate T-cell redirection, costimulatory activation and immune-checkpoint modulation within a single molecule, thereby facilitating the depletion of pathogenic B cells and potentially restoring immune homeostasis. According to CIC, GNC-038 is the world's first tetra-specific therapeutic antibody to enter clinical development. We are conducting two Phase I clinical trials of GNC-038 in China for rheumatoid arthritis and systemic lupus erythematosus, demonstrating the potential versatility of our GNC platform beyond oncology and into severe autoimmune diseases.

Innovative Radiopharmaceutical Platform: HIRE-ARC

Leveraging our expertise in antibody and ADC technologies, we have established the HIRE-ARC platform, a proprietary platform for the development of ARCs. The platform integrates precise antibody-mediated targeted delivery with the potent tumor-killing capabilities of radionuclides. Compared with conventional radioligand drug conjugates ("**RDCs**"), ARC candidates developed on our HIRE-ARC platform are designed to provide enhanced target specificity and tumor accumulation and may offer greater potential to overcome drug resistance.

As of the Latest Practicable Date, two drug candidates generated from our HIRE-ARC platform, BL-ARC001 and BL-ARC002, had entered Phase I clinical development for solid tumors in China. BL-ARC001 is our first innovative drug candidate in the ARC field and a potentially first-in-class ARC candidate. The clinical advancement of BL-ARC001 and BL-ARC002 demonstrates the ability of our HIRE-ARC platform to extend our antibody-engineering capabilities into innovative radiopharmaceutical modalities and further diversify our oncology pipeline.

OUR JOURNEY

Inception and Growth (1996 to 2010)

In 1996, Dr. Zhu Yi, our chairman, executive Director, general manager and Chief Scientific Officer, founded Sichuan Baili Pharmaceutical Co., Ltd. in Chengdu, the predecessor of our Company and currently one of our principal subsidiaries. At the time, China was gradually liberalizing its market-based approval regime for pharmaceutical manufacturers, encouraging domestic substitution of imported generic drugs and expanding its basic medical insurance system, which stimulated demand for domestically manufactured generic drugs and traditional Chinese medicines. Over the following years, we accumulated extensive expertise in complex generic drugs and traditional Chinese medicines and established a product portfolio covering therapeutic areas including anesthesia, parenteral nutrition, pediatrics and anti-infectives. More importantly, during this period, we developed into an integrated pharmaceutical group with capabilities spanning early-stage research, clinical development, manufacturing and commercialization, laying the operational and financial foundation for our subsequent transformation into an innovation-driven biopharmaceutical group.

Strategic Transformation (2010 to 2014)

Guided by our long-held aspiration to develop innovative drugs with breakthrough efficacy and bring them to patients worldwide, we made the strategic decision to enter the innovative drug sector in 2010 and commenced the independent development of oncology drugs with the potential to deliver breakthrough efficacy. To support this transformation, we reinvested a substantial portion of the revenue generated from our generic drug and traditional Chinese medicine businesses into innovative drug R&D. This strategic transformation was also aligned with China's policy initiatives at the time promoting emerging industries, including biotechnology and innovative drug development.

In 2014, we established SystImmune in Seattle, Washington, the United States, to spearhead our "0-to-1" breakthrough innovation and the discovery and development of our innovative drug pipeline. In the same year, we commenced the independent development of bispecific antibodies and ADCs. SystImmune has since served as the forefront of our global clinical development activities and our planned expansion into international commercialization. Our presence in the United States enabled us to assemble a high-caliber team with expertise in drug discovery, development and clinical research and to participate directly in one of the world's leading biotechnology innovation ecosystems, providing us with access to global talent, cutting-edge scientific knowledge and emerging industry trends. In parallel, we developed a team of scientists and experts in China dedicated to the R&D and accelerated clinical translation of innovative drugs.

Sustained Investment in Innovative Oncology Drug Discovery and Development (2014 to Present)

Since 2014, innovative drug discovery and development has been a principal focus of our business. This strategic transformation coincided with comprehensive reforms to China's drug review and approval system, including the introduction of priority review, conditional approval and breakthrough therapy designation. China's accession to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use in 2017 and the promulgation of the revised Drug Registration Regulation in 2020 further aligned China's technical guidelines, clinical-data acceptance standards and accelerated approval pathways with those of major global regulatory authorities, including the FDA and the European Medicines Agency. These reforms have contributed to shorter development and approval timelines for innovative drugs, particularly oncology biologics.

Against this backdrop, we committed substantial resources to the development of ADCs, bispecific antibodies and multi-specific antibodies. We established our SEBA and HIRE-ADC platforms in 2014 and our GNC multi-specific antibody platform in 2015, creating the technological foundation for our innovative drug pipeline. These investments have enabled us to achieve a number

of industry firsts, including the development of iza-bren, the only EGFR × HER3 bispecific ADC to have entered registrational stage globally, with two indications approved for marketing and one NDA for another indication accepted by the NMPA as of the Latest Practicable Date. Iza-bren has also pioneered the bispecific ADC field. Since its clinical progress was first reported, bispecific ADCs have attracted increasing industry attention and development activity globally, reinforcing our position at the forefront of this field. Building on our expertise in antibody and ADC technologies, we also established the HIRE-ARC platform and advanced two innovative ARC candidates into clinical development.

Our dual R&D centers in the United States and China are staffed by experienced professionals covering the full innovative drug development cycle, including drug discovery, preclinical development, chemistry, manufacturing and controls, clinical development and regulatory affairs. As of March 31, 2026, we had an R&D team of 1,702 members across our offices in China and the U.S., accounting for approximately 52.0% of our total employees. Members of our R&D team include scientists and industry professionals with experience leading drug discovery and development programs at MNCs, domestic biopharmaceutical companies and renowned research institutions, including MD Anderson Cancer Center and Fred Hutchinson Cancer Center, as well as professionals with experience working with the FDA. This combination of talent and expertise underpins our ability to discover, develop and advance innovative therapies globally.

Before becoming a publicly listed company, we attracted investment from established international healthcare investors, including OrbiMed. We successfully completed a listing of our Company on the SSE STAR Market in January 2023 and commenced a new chapter in our corporate development.

In December 2023, we entered into a global strategic license and collaboration agreement with BMS for iza-bren valued at up to US$8.4 billion, including an US$800 million upfront payment. The achievement of iza-bren represents the culmination of our sustained investment in innovative drug development, validates the global clinical and commercial potential of our internally developed oncology pipeline and marks our first major step in generating revenue from our innovative oncology drug portfolio.

In September 2025, we completed an A-share placement that raised gross proceeds of approximately RMB3.764 billion, providing additional financial resources to support the continued development of innovative drug candidates generated from our HIRE-ADC and GNC platforms.

The year 2026 marks the inaugural year of our quantum leap toward becoming an MNC — a defining milestone anchored by the commercial launch of our innovative drugs and a critical advance in our capability to independently conduct global Phase III clinical trials. On the commercialization front, iza-bren received NDA approvals from the NMPA for later-line treatment of NPC in June 2026 and for the second-line treatment of ESCC in July 2026. In addition, as of the Latest Practicable Date, iza-bren's NDA for TNBC had been accepted by the NMPA. On the clinical development front, this capability was underscored by the initiation of BL-M14D1's Phase III multi-regional clinical trial as first-line treatment for ES-SCLC — our first independently initiated global Phase III trial. These achievements together mark a critical inflection point in our transition from clinical development to commercialization, firmly establishing 2026 as the pivotal starting point of our journey toward becoming an entry-level MNC by 2030.

Our Future Roadmap

The biological complexity of cancer and its ability to evolve, develop treatment resistance, recur and progress make cancer treatment a continuing, long-term challenge. This challenge forces sustained efforts across the global biopharmaceutical industry to advance cancer therapies. Addressing it requires not only successive generations of therapies capable of delivering breakthrough efficacy, but also biopharmaceutical companies with the global capabilities and competitiveness to efficiently translate scientific innovation into clinical development, scaled manufacturing and commercialization and, ultimately, deliver such therapies to patients worldwide.

We aspire to become such a company and our strategic positioning is to remain firmly rooted in China, expand globally and become an MNC ("紮根中國、走向全球、成為跨國藥企"). Having substantially established our capabilities across global innovation, global clinical development, scaled manufacturing and commercialization, we have developed a clear action plan for 2026-2030, through which we aim to establish ourselves as an entry-level MNC by 2030. This plan is centered on the following three priorities:

Realize the global value of our existing pipeline. Centered on iza-bren, which we believe has super-blockbuster potential, we have built a broad and differentiated innovative oncology drug matrix. Iza-bren is our entry ticket to becoming an MNC. We intend to expand iza-bren across indications and geographies and advance other assets in our existing pipeline toward global development, registration and commercialization. Following the marketing approvals of iza-bren for NPC in June 2026 for ESCC in July 2026, and subject to continued clinical development and regulatory progress, we expect iza-bren to obtain marketing approvals in overseas markets in the coming years. Through these efforts, we aim to deliver an initial portfolio of breakthrough drugs to patients worldwide, while further strengthening the innovation, clinical development, manufacturing, supply and commercialization capabilities on a global scale that are required to operate as an MNC.

Lay the foundations for our next innovative oncology drug matrix with breakthrough efficacy. We will continue to pursue original "0-to-1" innovation across ADCs, ARCs and multi-specific TCEs by advancing the next-generation technology platforms and developing successive waves of internally generated candidates. These efforts are intended to establish, during the five-year period, the scientific, technological and pipeline foundations for our next innovative oncology drug matrix with breakthrough efficacy, anchored by another product with global super-blockbuster potential and supported by a deep and differentiated pipeline, to benefit patients worldwide.

Integrate internal and external breakthrough innovation. Leveraging the scientific know-how and industry insights accumulated through more than a decade of innovation and the MNC capabilities that we have, we will identify, evaluate, acquire or in-license high-quality external assets and systematically integrate them into our technology platforms, development capabilities and pipeline. By combining internally generated innovation with complementary external innovation, we aim to continuously strengthen and expand our innovation engine.

Looking beyond 2030, our strategic objective is to build on these foundations and evolve from an entry-level MNC into a fully-fledged, globally competitive MNC by 2035. To achieve this goal, we will remain focused on oncology, pursue breakthrough innovation to build a broad global pipeline of therapies with the potential to deliver breakthrough efficacy, and further develop comprehensive global operating capabilities.

OUR PORTFOLIO ASSETS

Our Innovative Drug Pipeline

We are a platform-driven biopharmaceutical group principally focused on discovering, developing and commercializing innovative oncology and other therapies worldwide. Leveraging our proprietary technology platforms — HIRE-ADC (and SEBA), GNC and HIRE-ARC, we have systematically built a global pipeline of innovative drug candidates across multiple modalities, targeting major tumor types and demonstrating the repeatable productivity of our discovery engine beyond any single product. As of the Latest Practicable Date, our innovative drug pipeline featured 15 clinical-stage drug candidates, five of which were undergoing clinical development outside China. All assets in our innovative drug pipeline as of the Latest Practicable Date are self-discovered.

Our Core Product, iza-bren, leads the innovative drug pipeline. Iza-bren is an EGFR × HER3 bispecific ADC that we believe has the potential to become a backbone pan-tumor treatment. As of the Latest Practicable Date, iza-bren had received NDA approvals from the NMPA for the late-line treatment of NPC and the second-line treatment of ESCC, while NDA for TNBC had been accepted by the NMPA. In addition, iza-bren was being evaluated in over 45 clinical trials across more than 10 major tumor types. Our other Core Product, T-Bren, an innovative HER2-specific ADC with the best-in-class potential to reshape treatment for multiple HER2-expressing solid tumors, is currently in pivotal registrational clinical trials.

The following chart sets forth an overview of our pipeline products as of the Latest Practicable Date.

	Product	Target	Indication	Mono/Combo	Pre-Clinical	IND	Phase Ia	Phase Ib	Phase II	Phase III	NDA	Approved for Marketing	Expected Completion Year[1]	Commercial Rights
HIRE-ADC	★ iza-bren	EGFR x HER3	NSCLC, SCLC, HR+/HER2- BC, TNBC, ESCC, GC, CRC, BTC, NPC, HNSCC, gynecological tumors, urological tumors and other solid tumors	Mono&Combo						*NPC and ESCC approved*			2026-2032[2]	China & U.S.[3]
	★ T-Bren	HER2	HER2+ BC, HER2- BC, GC, NSCLC, CC, OC, endometrial cancer, UC, BTC and other solid tumors	Mono&Combo									2026-2031	Global
	BL-M14D1	DLL3	SCLC, neuroendocrine tumors and other solid tumors	Mono&Combo									2026-2030	
	BL-M05D1	Claudin 18.2	GC/GEJ adenocarcinoma and other solid tumors	Mono									2026-2029	
	BL-M11D1	CD33	AML	Mono									2026-2028	
	BL-B16D1	Undisclosed	Lung cancer, BC, HNSCC and other solid tumors	Mono									2026	
	BL-M08D1	Undisclosed	Solid tumors and hematologic malignancies	Mono									2026-2027	
	BL-M09D1	Undisclosed	NSCLC, GIC and other solid tumors	Mono									2027	
	BL-M24D1	Undisclosed	Hematologic malignancies, NSCLC, HNSCC, GIC and other solid tumors	Mono									2027	
HIRE-ARC	BL-ARC001	Undisclosed	Lung cancer, BC, HNSCC, GIC and other solid tumors	Mono									2027	
	BL-ARC002	Undisclosed	Solid tumors	Mono									2027	
GNC	GNC-038	CD3 x 4-1BB x PD-L1 x CD19	Autoimmune diseases (systemic lupus erythematosus and rheumatoid arthritis, etc.)	Mono									2027	
SEBA	SI-B001	EGFR x HER3	NSCLC, HNSCC	Mono&Combo									2026-2027	
	SI-B003	PD-1 x CTLA-4	Solid tumors	Mono&Combo									2026	
	SI-B036	Undisclosed	Solid tumors	Mono									2028	

★ Core Products

Abbreviations: NSCLC: non-small cell lung cancer; SCLC: small cell lung cancer; BC: breast cancer; TNBC: triple-negative breast cancer; ESCC: esophageal squamous cell carcinoma; GC: gastric cancer; CRC: colorectal cancer; BTC: biliary tract cancer; NPC: nasopharyngeal carcinoma; HNSCC: head and neck squamous cell carcinoma; CC: cervical cancer; OC: ovarian cancer; UC: urothelial carcinoma; GEJ: gastroesophageal junction adenocarcinoma; AML: acute myeloid leukemia; GIC: gastrointestinal cancer; EC: esophageal cancer; HCC: hepatocellular carcinoma; RCC: renal cell carcinoma

Notes: (1) denotes estimated primary completion year; (2) in June 2026, the NMPA granted conditional approval for iza-bren for the treatment of NPC, based on data from the Phase III trial in r/m NPC (NCT06118333), which met its ORR primary endpoint in March 2025. In July 2026, the NMPA granted approval for iza-bren for the treatment of ESCC, based on data from the Phase III trial in r/m ESCC (NCT06304974), which met its dual primary endpoints of PFS and OS in October 2025; (3) we have entered into a global strategic license and collaboration agreement with BMS. Under this agreement, four joint committees have been established to govern and coordinate the collaboration. BMS and SystImmune will develop iza-bren in the United States in accordance with the global development plan and budget overseen by the joint steering committee and joint development committee. Commercialization of iza-bren in the United States will be conducted pursuant to a commercialization plan and budget jointly developed and finalized by BMS and SystImmune through the joint steering committee and joint commercialization committee. We have retained exclusive rights to develop and commercialize iza-bren in Chinese Mainland, and we have granted BMS an exclusive license to develop and commercialize iza-bren in the rest of the world, subject to certain specified conditions and limitations. For details of this agreement, see "— License and Collaboration Agreement with Bristol-Myers Squibb Company"; and (4) clinical progress represents the most advanced trial stage of the corresponding pipeline asset.

The following charts set forth our pipelines of iza-bren and T-Bren as of the Latest Practicable Date:

Clinical development of iza-bren in China

	Indication	Mono/Combo	Line of Therapy	Pre-Clinical	IND	Phase Ia	Phase Ib	Phase II	Phase III	NDA	Approved for Marketing	Expected Completion Year[1]	Clinical Trial Number
2 Approved	NPC	Mono	Later Line	★			Conditional approval in June 2026					2026[2]	NCT06118333
	ESCC	Mono	2L	★				Approval in July 2026				N/A[3]	NCT06304974
1 NDA	TNBC	Mono	2L+									2026	NCT06382142
11 Phase III	HR+/HER2- BC	Mono	3L+									2026	NCT06343948
	EGFRwt NSCLC	Mono	2L	★								2026	NCT06382129
	EGFRmut NSCLC	Mono	2L	★								2026	NCT06382116
	SCLC	Mono	2L	★								2026	NCT06500026
	EGFRmut NSCLC	Combo with osimertinib	1L									2028	NCT06838273
	UC	Mono	2L+	★								2027	NCT06857175
	OC	Mono	2L+	★								2027	NCT06994195
	ES-SCLC	Combo with PD-1	1L									2029	NCT07502300
	BTC	Mono	2L									2028	NCT07582315
	EGFRmut NSCLC	Combo with osimertinib	Maintenance treatment after chemoradiotherapy									2030	NCT07640789
	HR+/HER2- BC	Mono	2L									2028	NCT07648914
2 Phase II/III	ESCC	Combo with PD-1	1L									2028	NCT07554456
	EGFRmut NSCLC	Combo with osimertinib	Perioperative treatment									2032	NCT07642024
14 1L Phase II	EGFRmut NSCLC	Combo with osimertinib	1L									2027	NCT05880706
	Locally advanced or metastatic NSCLC	Combo with osimertinib	1L									2026	NCT06498986
	HNSCC and other solid tumors	Mono; combo with SI-B003	2L+; 1L & 2L+									2026	NCT06006169
	EC, GC, CRC and other GICS	Combo with SI-B003/PD-(L)1	1L & 2L+									2026	NCT06008054
	NSCLC, NPC, and other solid tumors	Combo with SI-B003	1L & 2L+									2026	NCT05956587
	UC	Combo with PD-(L)1	1L									2026	NCT06405425
	NSCLC, NPC and other solid tumors	Combo with PD-(L)1	1L & 2L+									2027	NCT06475300
	ES-SCLC	Combo with PD-(L)1	1L & 2L+									2026	NCT06437509
	HNSCC and other solid tumors	Combo with PD-(L)1	1L & 2L+									2027	NCT06437522
	TNBC	Combo with PD-(L)1	1L									2026	NCT06471205
	Advanced HCC	Combo with lenvatinib/ PD-(L)1±bevacizumab	1L & 2L+									2027	NCT06986785
	Advanced BTC	Combo with PD-(L)1 ± chemotherapy	1L & 2L+									2027	NCT06978114
	Advanced or metastatic RCC	Combo with axitinib/ lenvatinib ± PD-1	1L & 2L+									2027	NCT06962787
	CC and endometrial cancer	Combo with PD-1 ± bevacizumab	1L & 2L+									2027	NCT07054567
7 2L+ Phase II	Urinary system tumors and other solid tumors	Mono	2L+									2026	NCT05785039
	ES-SCLC	Mono; Combo with SI-B003	2L+									2026	NCT05924841
	CC and other gynecological malignancies	Mono; Combo with SI-B003	2L+									2026	NCT05990803
	UC and other solid tumors	Combo with SI-B003	2L+									2026	NCT05965856
	HER2- BC	Combo with SI-B003	2L+									2026	NCT06042894
	Recurrent glioblastoma	Mono	2L+									2026	NCT06598787
	Locally advanced or metastatic chordoma	Mono	2L+									2027	NCT06787664
4 Phase I/II[4]	Gynecological malignancies and other solid tumors	Mono	2L+									2026	NCT05803018
	Locally advanced or metastatic solid tumors	Mono	2L+									2026	NCT05194982
	Gastrointestinal tumors and other solid tumors	Mono	2L+									2026	NCT05262491
	BC and other solid tumors	Mono	2L+									2026	NCT05470348

★ *Included in breakthrough therapy designation program by the CDE*

Notes: (1) denotes estimated primary completion year; (2) we received conditional approval from the NMPA for iza-bren for the treatment of NPC in June 2026 based on data supporting the achievement of the ORR primary endpoint in March 2025, while follow-up for OS, the other primary endpoint, remained ongoing as of the Latest Practicable Date. Accordingly, the expected primary completion year for this trial remains 2026; (3) primary endpoints of this trial were reached in October 2025. We subsequently submitted an NDA for iza-bren for the treatment of ESCC in December 2025, which was approved in July 2026. Accordingly, the expected primary completion year for this trial is not applicable; and (4) comprises one Phase Ib/II trial and three Phase I trials.

Clinical development of iza-bren outside China

	Indication	Mono/Combo	Line of Therapy	Pre-Clinical	IND	Phase Ia	Phase Ib	Phase II	Phase III	NDA	Expected Completion Year[1]	Clinical Trial Number
1 Phase III	EGFRmut NSCLC	Combo with osimertinib	1L								2031	NCT07680790
3 Phase II/III	TNBC and ER-low/ HER2-negative BC	Mono	1L								2028	NCT06926868
	EGFRmut NSCLC	Mono	2L								2028	NCT07100080
	UC	Mono	2L+								2029	NCT07106762
2 Phase I/II[3]	NSCLC[2] and other solid tumors	Mono	2L+								2026	NCT05983432
	Solid tumors	Combo with osimertinib/ pembrolizumab/ nivolumab/ pumitamig	1L								2031	NCT06618287

Notes: (1) denotes estimated primary completion year; (2) In August 2025, FDA has granted breakthrough therapy designation to iza-bren for the treatment of locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations after failure of EGFR-TKI and platinum-based chemotherapy; and (3) comprises one Phase I trial and one Phase I/IIa trial.

Clinical development of T-Bren in China

	Indication	Mono/Combo	Line of Therapy	Pre-Clinical	IND	Phase I	Phase II	Phase III	Expected Completion Year[1]	Clinical Trial Number	Commercial Rights
8 Phase III	HER2+ BC	Mono	2L+						2026	NCT06316531	Global
	HER2-low recurrent/metastatic BC	Mono	2L+	★					2027	NCT06957886	
	HER2+ BC	Mono	Adjuvant therapy						2031	NCT06830889	
	HER2+ GC/GEJ	Mono	2L						2027	NCT07152405	
	HER2mut NSCLC	Mono	1L						2027	NCT07178795	
	HER2+ recurrent or metastatic BC	Combo with pertuzumab	1L						2029	NCT07518173	
	HER2-expressing OC, fallopian tube cancer and primary peritoneal cancer	Mono	2L+						2028	NCT07545460	
	HER2-expressing locally advanced or metastatic BTC	Mono	2L+						2028	NCT07606599	
1 Phase II/III	HER2+ BC	Combo with pertuzumab± chemotherapy	Neoadjuvant therapy						2028	NCT06891833	
3 Phase II	HER2+ BC	Combo with pertuzumab; Combo with pertuzumab and docetaxel	1L						N/A[2]	NCT06445400	
	HER2+ GC/GEJ	Combo with PD-(L)1±chemotherapy	1L						2026	NCT06423885	
	HER2-overexpressing non-squamous NSCLC	Combo with PD-1	1L						2027	NCT07264816	
3 Phase Ib/II	HER2-expressing urological and gastrointestinal cancers	Mono	2L+						2026	NCT06031584	
	HER2-expressing gynecological malignancies	Mono	2L+						2026	NCT06131450	
	HER2mut NSCLC	Mono	2L+						2026	NCT06114511	
2 Phase I	HER2+/HER2-low BC and other solid tumors	Mono	2L+						2026	NCT05461768	
	HER2-expressing gastrointestinal tumors and other solid tumors	Mono	2L+						2026	NCT05631964	

★ *Included in the breakthrough therapy designation list by the CDE*

Notes: (1) denotes estimated primary completion year; and (2) primary endpoints of this trial were reached in July 2025.

Clinical development of T-Bren outside China

	Indication	Mono/Combo	Line of Therapy	Pre-Clinical	IND	Phase I	Phase II	Phase III	Expected Completion Year[1]	Clinical Trial Number	Commercial Rights
1 Phase I	HER2-expressing solid tumors	Mono	2L+						2028	NCT06293898	Global

Note: (1) denotes estimated primary completion year.

Biologics Portfolio Empowered by the HIRE-ADC Platform

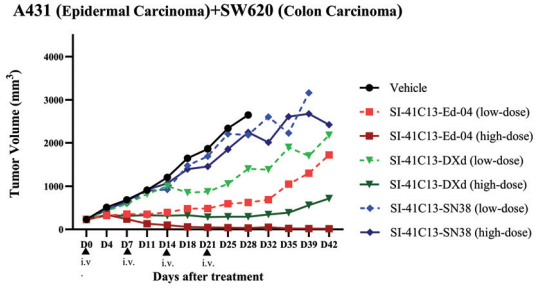
Short for "Heterogeneity overcoming — Immunogenic death inducing — Resistance antagonizing — Enhanced specificity," our self-developed HIRE-ADC platform is a fully integrated technology platform for ADC research and development. Leveraging this platform, we have developed and aim to continue developing drug candidates targeting novel antigens or with the potential to be best-in-class. With the HIRE-ADC platform, we have accrued a large volume of foundational research data, enabling continuous iteration of our innovative ADC technologies and development of our innovative drug portfolio. As of the Latest Practicable Date, our HIRE-ADC platform had produced nine clinical-stage ADC drugs, five of which had received investigational new drug ("**IND**") approvals from the FDA and were undergoing clinical trials. Key features of the HIRE-ADC platform are highlighted below.

- *Antibody.* We discover and develop proprietary mono/bispecific antibodies that are designed to achieve enhanced specificity and anti-tumor activity. For example, we have developed in-house the EGFR × HER3 bispecific antibody that is the antibody component of iza-bren. With this antibody, iza-bren has demonstrated stronger *in vivo* anti-tumor efficacy, compared to ADCs using the parental monoclonal antibodies targeting either EGFR or HER3 alone.

- *Linker.* Our in-house developed cleavable linkers are characterized by high stability. Our preclinical studies revealed that the DAR of T-Bren in plasma remained consistently above 7 after 21 days, in contrast to that of Enhertu (DS-8201, T-DXd) which declined from 7 to below 5 in the same timeframe, suggesting the superior stability of our linker in circulation.

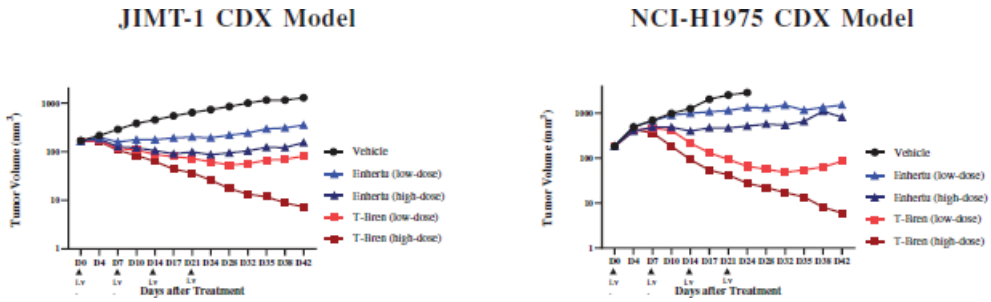
- *Payload*. We have developed proprietary cytotoxic payloads, such as Ed-04, characterized by effective induction of bystander effects and immunogenic cell death. Ed-04 is used in multiple of our clinical-stage assets, including iza-bren, T-Bren, BL-M11D1, BL-M05D1, BL-M14D1, BL-M08D1 and BL-M09D1. In an assay measuring the lipid-water partition coefficient in our preclinical studies, Ed-04 showed a higher logP compared to SN38 and DXd, which indicates greater cell membrane permeability and enhanced diffusion through tissues, thereby facilitating more effective bystander killing effects. Comparing an ADC using Ed-04 with two other ADCs that used the same antibody but different payloads, DXd and SN38, in a xenograft model, the ADC with Ed-04 achieved stronger tumor inhibition at the same dosage level compared to the other two ADCs.

Figure 1: Comparison of *in vivo* efficacy of payloads



Moreover, T-Bren (HER2 ADC with Ed-04) demonstrated stronger tumor inhibition compared to Enhertu at the same dosage level in *in vivo* studies.

Figure 2: Comparison of *in vivo* efficacy of T-Bren vs. Enhertu



Source: Company data

- *Conjugation*. Our conjugation technology supports both traditional non-specific and precise site-specific approaches, providing enhanced flexibility in ADC development. Our proprietary site-specific conjugation yields ADCs with superior tumor-killing efficacy, minimal aggregation, high conjugation efficiency, and enhanced molecular and plasma stability.

Iza-bren (EGFR × HER3 bispecific ADC), Our Core Product

Overview

Iza-bren is the world's first and only approved EGFR × HER3 bispecific ADC. Iza-bren received NDA approvals from the NMPA for the late-line treatment of NPC in June 2026 and for the second-line treatment of ESCC in July 2026. As of the Latest Practicable Date, iza-bren's NDA application for TNBC had been accepted by the NMPA, and it was being evaluated in over 45 clinical trials in China and overseas across over 10 tumor types, including NSCLC and BC, the two most prevalent tumor types in the world. Notably, we have observed efficacy in cancer patients who are unresponsive to or have progressed after PD-(L)1 treatment, a population with limited treatment options. Beyond NSCLC and BC, we are evaluating iza-bren in other EGFR/HER3-expressing tumors, including SCLC, head and neck squamous cell carcinoma ("**HNSCC**"), NPC, GC, colorectal cancer ("**CRC**"), biliary cancer, urothelial carcinoma ("**UC**"), gynecological cancers, renal cell carcinoma ("**RCC**") and hepatocellular carcinoma ("**HCC**"), as well as in additional combination regimens and earlier lines of therapy. To date, it has been studied in over 8,500 patients across various cancer types, making it one of the most investigated clinical-stage ADCs and underscoring its potential to become a backbone cancer therapy either as monotherapy or in combination with immunotherapy, targeted therapy or chemotherapy.

In December 2023, we entered into a global strategic license and collaboration agreement with BMS. Under the agreement, four joint committees have been established to govern and coordinate the collaboration. BMS and SystImmune will develop iza-bren in the United States in accordance with the global development plan and budget overseen by the joint steering committee and joint development committee. Commercialization of iza-bren in the United States will be conducted pursuant to a commercialization plan and budget jointly developed and finalized by BMS and SystImmune through the joint steering committee and joint commercialization committee. Both companies will share certain development expenses, profits and losses in the U.S. according to agreed-upon percentages, while we retain exclusive development and commercialization rights in Chinese Mainland, and BMS has exclusive rights outside of Chinese Mainland and the U.S. As of the Latest Practicable Date, we had received the upfront payment of US$800 million and the first clinical trial milestone of US$250 million. We expect to trigger the second clinical trial milestone in the fourth quarter of 2026. We are also eligible to receive additional milestone payments up to US$7.1 billion contingent on certain regulatory and sales milestones, for a total potential

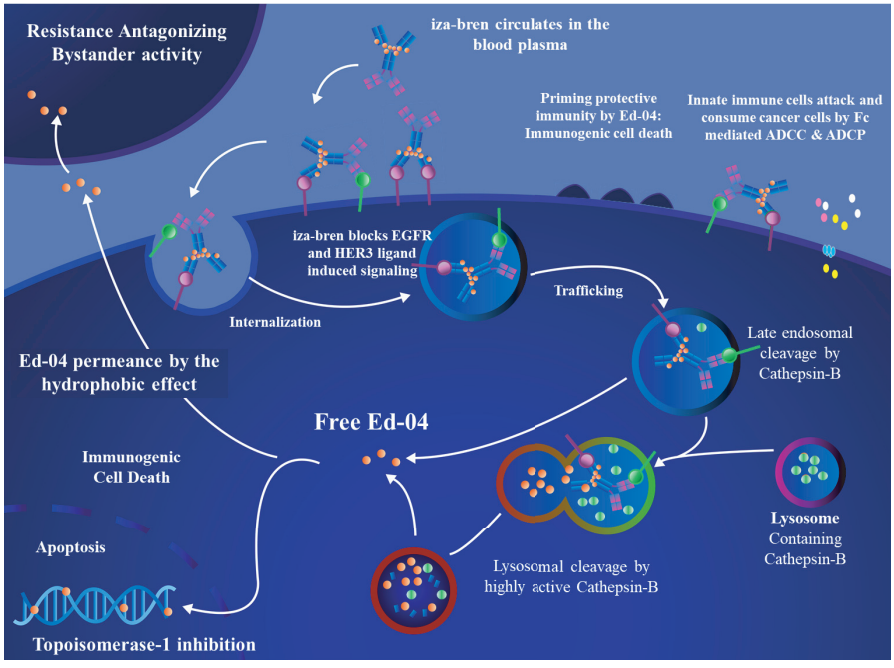
consideration of up to US$8.4 billion. We are eligible to receive tiered royalties on net sales outside of the U.S. and Chinese Mainland, while BMS is eligible to receive royalties on net sales in Chinese Mainland. For details, see "— License and Collaboration Agreement with Bristol-Myers Squibb Company."

Mechanism of Action

EGFR and HER3 are members of the HER family that regulate key cellular processes. Both receptors are over-expressed and frequently co-expressed across common epithelial carcinomas — including NSCLC, SCLC, BC, NPC, GC, CRC, HNSCC, EC and UC — making them well-established therapeutic targets with the potential to deliver pan-tumor efficacy.

Built on our SEBA and HIRE-ADC platforms, iza-bren is a bispecific ADC comprising an EGFR × HER3 bispecific antibody linked to a novel Topo1 inhibitor payload (Ed-04) via a cathepsin B cleavable linker. The symmetric tetravalent 2:2 scaffold increases avidity and specificity for both targets on cancer cells. By simultaneously binding EGFR and HER3, iza-bren blocks both homodimer and heterodimer signaling, enables better discrimination between cancerous and normal cells, drives efficient internalization and payload release, and reduces susceptibility to the bypass signaling and antigen escape that commonly drive resistance to single-antigen therapies.

Mechanism of Action of iza-bren



Market Opportunity and Competition

For the market information of major proposed indications covered by iza-bren, see "Industry Overview — The Oncology Drug Market." As of the Latest Practicable Date, there were 14 ADCs approved for nine solid tumor types, including BC, bladder cancer, GC, lung cancer, cervical cancer ("**CC**"), OC, EC and NPC, and iza-bren was the world's only approved EGFR × HER3 bispecific ADC.

Competitive Advantages

Encouraging clinical efficacy shown in the most prevalent cancer types. Iza-bren has demonstrated meaningful anti-tumor activity across multiple tumor types, including some of the most prevalent and difficult-to-treat cancers globally. The breadth and consistency of efficacy observed

across lung cancer, BC, NPC, gastrointestinal cancer ("**GIC**"), UC and OC, together with the marketing approvals and achievement of primary endpoints in Phase III registrational trials, support the potential of iza-bren as a backbone therapy in oncology. Some highlights of its clinical efficacy are summarized below. For additional information, see "— Summary of Clinical Trial Data."

- NSCLC. Lung cancer is the most common type of cancer and the leading cause of cancer-related death globally, with NSCLC accounting for approximately 85% of all lung cancer cases. In NSCLC, iza-bren has demonstrated robust efficacy as a monotherapy and in combination regimens.

  - Monotherapy. In our Phase I trial (NCT05194982), iza-bren monotherapy demonstrated robust efficacy across NSCLC populations, including patients with EGFRmut NSCLC post-TKI therapy (ORR of 66.0%, mPFS of 12.5 months, 18-month OS rate of 69.2%), EGFRwt NSCLC post-immunotherapy/chemotherapy, and patients with driver gene alterations beyond classical EGFR mutations (ORR of 46.2%, mPFS of 7.0 months). A global Phase Ib trial (NCT05983432) confirmed antitumor activity in patients outside China. Based on these results, we have initiated Phase III registrational trials in China for second-line EGFRwt and EGFRmut NSCLC (NCT06382129, NCT06382116), and a global Phase II/III trial for second-line EGFRmut NSCLC (NCT07100080). Iza-bren monotherapy was granted breakthrough therapy designation by the CDE for second-line EGFRwt and EGFRmut NSCLC in September 2024, and by the FDA for previously treated EGFRmut NSCLC in August 2025.

  - Combination therapy. In our Phase II study (NCT05880706), iza-bren plus osimertinib as first-line therapy achieved an ORR of 100% (confirmed ORR of 95%) and a DCR of 100% in 40 evaluable EGFRmut NSCLC patients, with a 12-month PFS rate of 92.1% and a 12-month OS rate of 94.8%. These results highlight the potential of this combination to redefine the standard of care in first-line EGFRmut NSCLC. A Phase III trial (NCT06838273) was initiated in China in February 2025.

- SCLC. Iza-bren was granted breakthrough therapy designation for SCLC by the CDE in January 2025. In our Phase I trial (NCT05194982), iza-bren demonstrated promising efficacy in 58 patients with locally advanced or metastatic SCLC post-progression, achieving an ORR of 55.2%, a DCR of 81.0%, an mPFS of 4.0 months, and an mOS of 12.0 months. In patients who had received only prior first-line PD-(L)1 inhibitor plus platinum-based chemotherapy, iza-bren achieved an ORR of 80.0% (confirmed ORR of 75.0%), an mPFS of 6.9 months, and an mOS of 15.0 months. Clinical benefit was observed regardless of platinum sensitivity or prior irinotecan treatment. We have initiated a Phase III trial (NCT06500026) for recurrent SCLC in China.

- BC. Iza-bren has demonstrated promising responses regardless of HER2 expression in heavily pretreated patients with TNBC or HR+/HER2- BC. In our Phase I trial (NCT05470348), TNBC patients achieved an ORR of 34.1% (50.0% in patients with 1-2 prior chemotherapy lines), and HR+/HER2- BC patients achieved an ORR of 46.8% (54.3% in patients with 1-2 prior chemotherapy lines). In our Phase III trial (NCT06382142) for TNBC post 1-2 prior systemic therapies, iza-bren demonstrated a statistically significant improvement in PFS (median 8.5 vs. 3.1 months; HR=0.29; P<0.0001) and OS (median 15.9 vs. 12.5 months; HR=0.60; P=0.0019) versus chemotherapy, with consistent benefit regardless of HER2 expression status. We submitted an NDA for TNBC to the NMPA in May 2026, which had been accepted for filing as of the Latest Practicable Date. Iza-bren is also being evaluated in a Phase III trial for HR+/HER2- BC in China (NCT06343948) and a global pivotal Phase II/III registrational trial for TNBC (NCT06926868).

- NPC. In our Phase I trial (NCT05194982), iza-bren achieved an ORR of 59.5% and a DCR of 100% among 37 evaluable NPC patients with a median of three prior treatment lines. In our Phase III trial (NCT06118333), which achieved its primary endpoint at interim analysis in July 2025, iza-bren demonstrated clear superiority over chemotherapy in ORR (54.6% vs. 27.0%) and mPFS (8.38 vs. 4.34 months). These results were selected as a Late-Breaking Abstract at the ESMO Congress 2025. Iza-bren was granted breakthrough therapy designation by the CDE in April 2024, and we received the NDA approval from the NMPA for the later-line treatment of NPC in June 2026.

- ESCC. In ESCC, our Phase III trial (NCT06304974) showed clear superiority over chemotherapy in PFS (4.17 vs. 1.97 months; HR=0.50; P<0.0001) and OS (9.79 vs. 7.20 months; HR=0.64; P=0.0004), with results presented at the 2026 ASCO Annual Meeting. We received the NDA approval from the NMPA for the second-line treatment of ESCC in July 2026.

- Other Solid Tumors. Iza-bren has also demonstrated encouraging efficacy across UC and OC. In UC, our Phase II trial (NCT05785039) achieved an ORR of 40.7% (75.0% in patients with one prior line), with a Phase III trial (NCT06857175) ongoing. In OC, our Phase Ib/II and Phase II trials (NCT05803018, NCT05990803) achieved an ORR of 53.1% and mPFS of 7.0 months in 96 evaluable patients, with a Phase III trial (NCT06994195) ongoing. Iza-bren was granted breakthrough therapy designations by the CDE for UC and OC in September 2025.

Manageable safety profile. Iza-bren's differentiated design translates into a manageable safety and tolerability profile in multiple clinical trials. By selectively binding tumor cells that co-express EGFR and HER3, and releasing its cytotoxic payload only after internalization via the cleavable linker, iza-bren localizes therapeutic activity at the tumor site while sparing healthy tissue. This minimizes systemic exposure and on-target, off-tumor toxicity, reducing the risk of toxicities commonly associated with conventional chemotherapies and widening the therapeutic window. To date, iza-bren has been administered to over 8,500 patients across multiple clinical trials, covering more than 10 tumor types. In studies of various cancers, iza-bren has consistently demonstrated a favorable safety and tolerability profile. Treatment-related adverse events ("**TRAEs**") were primarily hematologic in nature and clinically manageable, with ILD reported only in rare cases. These safety data suggest that iza-bren holds strong potential to offer a well-tolerated and safe therapeutic option for cancer patients.

Pan-cancer treatment potential. Based on encouraging efficacy and safety data, we are developing iza-bren as a potential pan-cancer therapy, either as monotherapy or in combination with immunotherapy, targeted therapy, or chemotherapy. As of the Latest Practicable Date, iza-bren was being evaluated in over 45 clinical trials across China and overseas for over 10 tumor types, with over 8,500 patients enrolled — making it one of the most extensively investigated clinical-stage ADCs globally. Its program includes 14 Phase III trials (EGFRwt NSCLC, EGFRmut NSCLC, SCLC, HR+/HER2- BC, TNBC, ESCC, NPC, UC and OC) and two Phase II/III registrational trials (ESCC and EGFRmut NSCLC) in China, as well as three global pivotal Phase II/III registrational trials (TNBC, NSCLC and UC). In addition, a global Phase III clinical trial for EGFRmut NSCLC is expected to be initiated in September 2026. Iza-bren is being evaluated across treatment lines — from late-line to first-line and neoadjuvant/adjuvant settings — positioning it as a potential backbone cancer therapy across multiple solid tumors.

Collaboration with BMS to accelerate iza-bren's global development and expansion. Our collaboration with BMS, a global biopharmaceutical leader with US$48.2 billion in revenue in 2025, brings together the expertise and resources of two industry leaders and accelerates the development of iza-bren towards commercialization. Leveraging BMS's established clinical development capabilities outside of Chinese Mainland, this partnership can advance the development of iza-bren's global clinical development plans for a spectrum of cancers. In addition, we view this arrangement as a valuable catalyst for our growth. By combining our synergistic capabilities, we believe this strategic collaboration will maximize the clinical and market potential of iza-bren on a global scale.

Summary of Clinical Trial Data

The below table summarizes the details of trials for iza-bren in China:

Indication	Type of therapy	Trial phase	Trial start date	(Expected) trial end year[(1)]
Lung Cancer				
Unresectable locally advanced or metastatic EGFRwt NSCLC (NCT06382129)	Mono	Phase III	May 2024	(2026)
Locally advanced or metastatic EGFRmut NSCLC (NCT06382116)	Mono	Phase III	May 2024	(2026)
Recurrent SCLC (NCT06500026)	Mono	Phase III	August 2024	(2026)
EGFRmut NSCLC (NCT06838273)	Combo with osimertinib	Phase III	February 2025	(2028)
ES-SCLC (NCT07502300)	Combo with PD-1	Phase III	June 2026	(2029)
EGFRmut NSCLC after platinum-based chemoradiotherapy as maintenance treatment (NCT07640789)	Combo with osimertinib	Phase III	2026Q3	(2030)
EGFRmut NSCLC (perioperative treatment) (NCT07642024)	Combo with osimertinib	Phase II/III	July 2026	(2032)
EGFRmut NSCLC (NCT05880706)	**Combo with osimertinib**	**Phase II**	**July 2023**	**(2027)**
Locally advanced or metastatic NSCLC, NPC and other solid tumors (NCT05956587)	Combo with SI-B003	Phase II	January 2024	(2026)
Locally advanced or metastatic NSCLC, NPC and other solid tumors (NCT06475300)	Combo with PD-(L)1	Phase II	June 2024	(2027)
Locally advanced or metastatic NSCLC (NCT06498986)	Combo with osimertinib	Phase II	July 2024	(2026)
ES-SCLC (NCT05924841)	Mono; combo with SI-B003	Phase II	November 2023	(2026)
ES-SCLC (NCT06437509)	Combo with PD-(L)1	Phase II	June 2024	(2026)

Indication	Type of therapy	Trial phase	Trial start date	(Expected) trial end year[1]
BC				
Unresectable locally advanced, recurrent or metastatic HR+/HER2- BC (NCT06343948)	Mono	Phase III	April 2024	(2026)
Unresectable locally advanced or metastatic TNBC (NCT06382142)	**Mono**	**Phase III**	**June 2024**	**(2026)[2]**
Unresectable locally advanced, recurrent or metastatic HR+/HER2- BC (NCT07648914)	Mono	Phase III	July 2026	(2028)
Unresectable locally advanced or recurrent metastatic TNBC (NCT06471205)	Combo with PD-(L)1	Phase II	August 2024	(2026)
HER2- BC (NCT06042894)	Combo with SI-B003	Phase II	December 2023	(2026)
Unresectable locally advanced or metastatic BC and other solid tumors (NCT05470348)	**Mono**	**Phase I**	**August 2022**	**(2026)[3]**
GIC				
Recurrent or metastatic ESCC (NCT06304974)	**Mono**	**Phase III**	**March 2024**	**October 2025[4]**
Advanced biliary tract cancer ("**BTC**") after failure of platinum chemotherapy and PD-1/PD-L1 antibody therapy (NCT07582315)	Mono	Phase III	June 2026	(2028)
ESCC (NCT07554456)	Combo with PD-1	Phase II/III	June 2026	(2028)
Locally advanced or EC, GC, CRC and other GICs (NCT06008054)	Combo with SI-B003/PD-(L)1	Phase II	November 2023	(2026)
Locally advanced or metastatic GIC and other solid tumor (NCT05262491)	**Mono**	**Phase I**	**February 2022**	**(2026)[5]**
Other cancer types				
Recurrent or metastatic NPC (NCT06118333)	**Mono**	**Phase III**	**December 2023**	**(2026)[6]**
Recurrent or metastatic UC (NCT06857175)	Mono	Phase III	March 2025	(2027)

Indication	Type of therapy	Trial phase	Trial start date	(Expected) trial end year[(1)]
Recurrent epithelial OC (NCT06994195)	Mono	Phase III	August 2025	(2027)
Recurrent or metastatic HNSCC and other solid tumors (NCT06006169)	Mono; combo with SI-B003	Phase II	October 2023	(2026)
Recurrent or metastatic HNSCC and other solid tumors (NCT06437522)	Combo with PD-(L)1	Phase II	June 2024	(2027)
Recurrent or metastatic gynecological malignancies and other solid tumors (NCT05803018)	**Mono**	**Phase Ib/II**	**June 2023**	**(2026)**
Recurrent or metastatic CC and other gynecological malignancies (NCT05990803)	**Mono; combo with SI-B003**	**Phase II**	**November 2023**	**(2026)**
Recurrent or metastatic CC and endometrial cancer (NCT07054567)	Combo with PD-1 ± bevacizumab	Phase II	August 2025	(2027)
Recurrent glioblastoma (NCT06598787)	Mono	Phase II	October 2024	(2026)
Multiple solid tumors, including locally advanced or metastatic urinary system tumors and other solid tumors (NCT05785039)	**Mono**	**Phase II**	**April 2023**	**(2026)**
Locally advanced or metastatic UC and other solid tumors (NCT05965856)	Combo with SI-B003	Phase II	December 2023	(2026)
Locally advanced or metastatic UC (NCT06405425)	Combo with PD-(L)1	Phase II	May 2024	(2026)
Advanced HCC (NCT06986785)	Combo with lenvatinib/PD-(L)1 ±bevacizumab	Phase II	June 2025	(2027)
Advanced or metastatic RCC (NCT06962787)	Combo with axitinib/lenvatinib ± pembrolizumab	Phase II	July 2025	(2027)
Advanced BTC (NCT06978114)	Combo with pembrolizumab ± chemo	Phase II	June 2025	(2027)
Locally advanced or metastatic chordoma (NCT06787664)	Mono	Phase II	January 2025	(2027)
Locally advanced or metastatic solid tumor (NCT05194982)	**Mono**	**Phase I**	**November 2021**	**(2026)[(7)]**

Notes: (1) denotes estimated primary completion year; (2) primary endpoints of this trial reached in January 2026. We submitted an NDA for iza-bren for the treatment of TNBC to the NMPA in May 2026, which had been accepted for filing as of the Latest Practicable Date; (3) primary endpoints of TNBC cohort were reached in December 2023;

(4) primary endpoints of this trial were reached in October 2025. We subsequently submitted an NDA for iza-bren for the treatment of ESCC in December 2025, which was approved in July 2026; (5) primary endpoints of ESCC cohort were reached in November 2023; (6) we received conditional approval from the NMPA for iza-bren for the treatment of NPC in June 2026 based on data supporting the achievement of the ORR primary endpoint in March 2025, while follow-up for OS, the other primary endpoint, remained ongoing as of the Latest Practicable Date. Accordingly, the expected primary completion year for this trial remains 2026; and (7) primary endpoints for NPC cohort were reached in July 2023.

The table below summarizes the details of trials for iza-bren outside China:

Indication	Type of therapy	Trial phase	(Expected) trial start date	(Expected) trial end year[(1)]
EGFRmut NSCLC (NCT07680790)	Combo with osimertinib	Phase III	(September 2026)	(2031)
EGFRmut NSCLC (NCT07100080)	Mono	Phase II/III	November 2025	(2028)
UC (NCT07106762)	Mono	Phase II/III	September 2025	(2029)
TNBC and ER-low/HER2-negative BC (NCT06926868)	Mono	Phase II/III	September 2025	(2028)
Advanced solid tumors (NCT06618287)	Combo with osimertinib/ pembrolizumab/ nivolumab/ pumitamig	Phase I/IIa	February 2025	(2031)
Metastatic or unresectable NSCLC and other solid tumors (NCT05983432)	**Mono**	**Phase I**	**August 2023**	**(2026)**

Note: (1) denotes estimated primary completion year.

Key clinical trial results are summarized below. The relevant trials are marked in bold in the table above. These selected trials either established the preliminary clinical efficacy and safety of iza-bren for the relevant indications or are registrational trials supporting NDA submissions. With the NDA approvals for NPC and ESCC in June and July 2026, respectively, and multiple Phase III registrational trials ongoing across diverse tumor types, we have advanced iza-bren well beyond the concept stage and demonstrated significant clinical and commercial promise.

The First-in-Human Phase I Trial for Various Solid Tumors and Trials on Lung Cancer

Phase I Clinical Trial of Iza-bren as Monotherapy for Locally Advanced or Metastatic Solid Tumors (NCT05194982)

This is a first-in-human, open-label, multicenter Phase I clinical trial to evaluate the efficacy of iza-bren as monotherapy in patients with locally advanced or metastatic NSCLC, NPC and other solid tumors. The primary endpoints for this trial are dose-limiting toxicity ("**DLT**"), maximum tolerated dose ("**MTD**") and recommended phase 2 dose ("**RP2D**"). The secondary endpoints are pharmacokinetics ("**PK**"), anti-drug antibody, ORR, DCR, and duration of response ("**DoR**"). The exploratory endpoints include PFS, OS, biomarkers, and neutralizing antibodies (nAb). The encouraging efficacy and safety results were published in July 2024 in the globally renowned academic journal, *The Lancet Oncology*. We initiated this Phase I study in November 2021. The

study includes Phase Ia (dose escalation) and Phase Ib (dose expansion) parts. Phase Ia was completed in September 2022. The Phase Ib (dose expansion) stages for NSCLC and SCLC cohorts were completed in November 2023 in terms of reaching primary endpoints.

The Phase Ib (dose expansion) stage for NPC cohort was completed in July 2023 in terms of reaching primary endpoints. For details regarding key clinical trial results for NPC, see "— Phase III Clinical Trial of Iza-bren as Monotherapy for Recurrent or Metastatic NPC (NCT06118333)." Below is a summary of key clinical trial results for NSCLC and SCLC in the Phase I trial.

1. NSCLC

(i) Iza-bren as Monotherapy for Patients with NSCLC Having Progressed After the Standard of Care

Trial Design. This study includes patients with locally advanced or metastatic NSCLC and other solid tumors who have a performance status score of 0 or 1 according to the Eastern Cooperative Oncology Group ("**ECOG**") and have at least one measurable lesion per response evaluation criteria in solid tumors version 1.1 ("**RECIST v1.1**"). These patients must have either failed standard therapy or have no feasible treatment available. As of the data cut-off date (August 17, 2023), the dose escalation stage was performed on a 21-day cycle, in which 13 subjects received iza-bren at the dosage of 2.5 mg/kg, 3.0 mg/kg and 3.5 mg/kg D1D8 every three weeks ("**Q3W**"), and six subjects received iza-bren at the dosage of 5.0 mg/kg, and 6.0 mg/kg D1 Q3W. In the dose-expansion stage, subjects received iza-bren with the same dosing levels and schedules as in the dose escalation stage.

We evaluated the efficacy of iza-bren as monotherapy for the treatment of NSCLC based on the data from response-evaluable patients enrolled between December 8, 2021 and March 13, 2023. Patients enrolled after March 13, 2023 were not included due to the short follow-up period as of the data cut-off date (August 17, 2023).

Efficacy Data. As of the data cut-off date (August 17, 2023), there were 75 response-evaluable NSCLC patients with treated or without central nervous system ("**CNS**") metastasis administered with iza-bren. Among these patients, the interim Phase I results showed an ORR of 52.0%, cORR of 41.3%, DCR of 86.7%, mDoR of 12.3 months and mPFS of 6.8 months.

Notably, iza-bren achieved greater efficacy in 13 EGFRmut NSCLC patients with treated or without CNS metastasis, who received the dosages at 2.5mg/kg D1D8 Q3W and 4.5mg/kg D1 Q3W, with an ORR of 69.2%, cORR of 61.5%, DCR of 92.3%, mDoR of 12.3 months and mPFS of 15.0 months. In addition, 26 of the enrolled EGFRwt NSCLC patients received iza-bren as a systemic 2L treatment, showing an ORR of 50.0%, cORR of 38.5%, DCR of 80.8% and mPFS of 6.7 months.

Safety Data. As of the data cut-off date (August 17, 2023), iza-bren demonstrated a manageable safety profile in previously treated patients with solid tumors. Among 369 enrolled patients with NSCLC, NPC and other solid tumors, 351 patients (95%) experienced TRAE. 226 patients (61%) experienced Grade 3 or above TRAE, 115 patients (31%) experienced Grade 4 or above TRAE, 108 patients (29%) experienced serious TRAE, and eight patients died due to TRAE. The incidence of ILD is low, with only one case of Grade 2 ILD observed.

(ii) Iza-bren as Monotherapy for Patients with Locally Advanced or Metastatic EGFRmut NSCLC

Trial Design. As of the data cut-off date (June 30, 2025), a total of 171 patients with EGFRmut NSCLC had been enrolled across two study cohorts, each with a different dosing scheme. In the first cohort, 5, 22, 121, and 43 patients received iza-bren at doses of 2.0 mg/kg, 2.3 mg/kg, 2.5 mg/kg, and 3.5 mg/kg, respectively, administered on a D1D8 Q3W schedule. In the second cohort, 9, 8, and 4 patients received iza-bren at doses of 4.5 mg/kg, 5.0 mg/kg, and 6.0 mg/kg, respectively, on a D1 Q3W schedule.

Efficacy Data. As of the data cut-off date (June 30, 2025), efficacy data from the 171 EGFRmut NSCLC patients demonstrated that iza-bren monotherapy achieved an ORR of 57.9%, a cORR of 47.4%, a mPFS of 6.9 months, and a mOS of 24.8 months. Efficacy outcomes for each cohort are summarized in the table below.

		2.5 mg/kg D1D8Q3W		
	Total	**Total**	**Post any TKI & chemo naive***	**Post 3G TKI & chemo naive**
	(N=171)	*(N=121)*	*(N=50)*	*(N=46)*
Median (range) LoT	2 (1-10)	2 (1-10)	2 (1-5)	2 (1-5)
BOR				
PR	99 (57.9)	68 (56.2)	33 (66.0)	30 (65.2)
Confirmed PR	81 (47.4)	59 (48.8)	28 (56.0)	25 (54.3)
PR pending confirmation[(1)]	3 (1.8)	1 (0.8)	1 (2.0)	1 (2.2)
SD	40 (23.4)	30 (24.8)	12 (24.0)	12 (33.3)
PD	26 (15.2)	19 (15.7)	4 (8.0)	3 (6.5)
NE[(2)]	6 (3.5)	4 (3.3)	1 (2.0)	1 (2.2)
ORR, % (95%CI)	57.9 (50.1, 65.4)	56.2 (46.9, 65.2)	66.0 (51.2, 78.8)	65.2 (49.8, 78.6)
cORR, % (95%CI)	47.4 (39.7, 55.1)	48.8 (39.6, 58.0)	56.0 (41.3, 70.0)	54.3 (39.0, 69.1)
DCR, % (95%CI)	81.3 (74.6, 86.8)	81.0 (72.9, 87.6)	90.0 (78.2, 96.7)	91.3 (79.2, 97.6)
Median DoR, mo (95%CI)	8.5 (6.9, 11.2)	8.5 (6.5, 12.7)	13.7 (5.5, 19.5)	12.7 (5.5, NR)
Median PFS, mo (95%CI)	6.9 (5.5, 9.6)	6.9 (5.5, 9.7)	12.5 (6.9, 18.0)	12.5 (6.9, 18.0)
Median OS, mo (95% CI)	24.8 (18.5, NR)	24.8 (18.0, NR)	NR (NR, NR)	NR (NR, NR)
Median FU for OS, mo (95% CI)	20.5 (18.3, 21.9)	21.9 (20.3, 22.7)	20.5 (15.8, 21.9)	20.5 (15.8, 21.9)

Notes: * Chemo naive was defined as no prior chemotherapy in the advanced or metastatic setting.

(1) Refers to patients still on study with tumor assessment of PR and not reach to the next time point of tumor assessment;
(2) Including patients without post-baseline tumor assessment.

Notably, in the cohort receiving iza-bren at a dose of 2.5 mg/kg, the treatment demonstrated particularly strong efficacy in 50 patients with EGFRmut NSCLC who had previously received EGFR-TKI therapy but had not undergone chemotherapy. As of the data cut-off date (June 30, 2025), iza-bren monotherapy in this subgroup achieved an ORR of 66.0%, a cORR of 56.0% (including one unconfirmed partial response ("**PR**")), and a DCR of 90.0%. The mDoR was 13.7 months, and the mPFS was 12.5 months. At a median follow-up of 20.5 months, the mOS had not yet been reached. Among these 50 patients, 94.0% experienced tumor shrinkage, with a median reduction of –38.9% (range: -81.3% to -0.7%).

Within this subgroup, similar efficacy was observed across different EGFR mutation subtypes, consistent with the overall population. Specifically, among the 50 patients, 31 had EGFR exon 19 deletion mutations and 17 had EGFR L858R mutations. The exon 19 deletion group achieved a mPFS of 14.1 months and a DCR of 90.3%, while the L858R mutation group had a mPFS of 12.5 months and a DCR of 88.2%.

Safety Data. Iza-bren demonstrated a favorable safety profile. As of the data cut-off date (June 30, 2025), the most common Grade ≥3 adverse events were hematologic toxicities. Only 1.2% of patients discontinued treatment due to TRAEs. Grade ≥3 neutropenia resolved rapidly, with a median duration of 4–6 days, and the incidence of febrile neutropenia was low at 1.8%. No new safety signals were identified.

(iii) Iza-bren as Monotherapy for Patients with Locally Advanced or Metastatic NSCLC with Driver Gene Alterations (GA) Outside of Classic EGFR Mutations

Trial Design. This study includes the expansion cohorts of patients with locally advanced or metastatic NSCLC with presence of driver GA outside of classic EGFR mutations (19del and L858R), each defined by a pre-specified GA, including EGFR exon 20 insertions, non-classical EGFR mutations, mutations in HER2, anaplastic lymphoma kinase ("**ALK**"), ROS1, B-Raf proto-oncogene serine/threonine kinase ("**BRAF**") (V600E and others), KRAS (G12C and others), SMARCA4, MET (Exon 14), RET, and NTRK. They must have a performance status score of 0 or 1 according to the ECOG and at least one measurable lesion per RECIST v1.1. They also must have failed standard treatment and received no more than one prior line of chemotherapy. Iza-bren was administered at a dosage of 2.5 mg/kg, D1D8 Q3W.

A total of 83 patients with non-classical driver GA beyond classic EGFR mutations were enrolled in the study as of the data cut-off date on March 28, 2025. In terms of prior treatment history, 67.5% of patients had received first-line therapy, 18.1% had received second-line therapy, and 14.5% had undergone third-line or later treatments. The proportions of patients previously treated with platinum-based chemotherapy, PD-(L)1 inhibitors, and targeted therapies were 74.7%, 50.6%, and 51.8%, respectively.

Efficacy Data. As of the data cut-off date on March 28, 2025, among 78 evaluable patients with non-classical driver GA in this trial, the ORR was 46.2%, with a cORR of 39.7% and DCR of 85.9%. The mPFS was 7.0 months, while both the median mDoR and mOS had not yet been reached. Notably, among 13 patients with EGFR exon 20 insertions or other uncommon EGFR mutations, the cORR reached 69.2%, DCR was 92.3%, and mPFS was 10.5 months, with mDoR and mOS still pending. Among 17 patients in the HER2-mutant subgroup, the cORR was 52.9%, DCR was 100%, mDoR was 5.7 months, and mPFS was 7.5 months, while mOS had not yet been reached.

Overall, 81.3% of patients in this cohort experienced tumor shrinkage, with a median reduction of 29.2%. Several patients achieved durable responses, with some maintaining tumor remission for up to 18 months.

Safety Data. As of the data cut-off date on March 28, 2025, among 83 enrolled patients in this trial, iza-bren demonstrated a favorable profile. The most common Grade ≥3 TRAEs were hematologic toxicities, which were effectively managed through supportive care or dose adjustments. The treatment discontinuation rate due to TRAEs was low, at only 2.4%.

2. SCLC — Iza-bren as Monotherapy for Patients with Locally Advanced or Metastatic SCLC

Trial Design. Patients with locally advanced or metastatic SCLC who experienced disease progression after prior systemic therapy were enrolled. Eligible patients received iza-bren at doses of 2.0 or 2.5 mg/kg (D1D8 Q3W) or 4.5 or 5.0 mg/kg (D1 Q3W). Tumor assessments were conducted every six weeks. Efficacy analyses were performed in the overall cohort as well as in pre-defined subgroups, with a focus on patients with limited prior therapy exposure.

Efficacy Data. As of the data cut-off date (December 5, 2024), among the 58 evaluable patients, iza-bren achieved an ORR of 55.2% and a confirmed ORR of 44.8%, with a median PFS of 4.0 months and a median OS of 12.0 months.

In the 2.5 mg/kg cohort, which included 52 patients, 20 patients had received only one prior line of platinum-based chemotherapy plus PD-(L)1 inhibitor. In this subgroup, iza-bren achieved an ORR of 80.0% and a confirmed ORR of 75.0%, with a median DoR of 5.6 months, a median PFS of 6.9 months and a median OS of 15.0 months.

Safety Data. As of the data cut-off date (December 5, 2024), iza-bren demonstrated a manageable safety profile in patients with SCLC. The most common hematologic TRAEs of any grade were anemia (84.5%), leukopenia (74.1%), thrombocytopenia (72.4%) and neutropenia (70.7%). The most common non-hematologic TRAEs were asthenia (41.4%), hypoalbuminemia (39.7%), stomatitis (34.5%), nausea (31.0%) and vomiting (31.0%). Grade ≥3 TRAEs were predominantly hematologic in nature and could be managed with supportive measures or dose modifications. The TRAE-related discontinuation rate was 12.1%. Two iza-bren-related fatal events were reported, including one case of respiratory failure and one case of gastrointestinal infection. No ILD events or new safety signals were observed.

Phase II Clinical Trial of Iza-bren in Combination with Osimertinib for Locally Advanced or Metastatic EGFRmut NSCLC (NCT05880706)

This is a Phase II clinical study to evaluate the efficacy and safety of iza-bren in combination with osimertinib mesylate tablets in patients with locally advanced or metastatic EGFRmut NSCLC. The primary endpoints for this trial are RP2D and ORR, and the secondary endpoints are PFS, DCR, DoR and treatment-emergent adverse events ("**TEAEs**"). Exploratory endpoints are PK, Nab, DDI, OS and biomarker.

Trial Design. This study includes treatment-naïve patients with locally advanced or metastatic EGFRmut NSCLC. These patients must have a performance status score of 0 or 1 according to the ECOG and have measurable disease per RECIST v1.1. During the trial, patients were assigned into two cohorts. In one cohort, 41, 40 and 42 patients received iza-bren in combination with osimertinib at 2.2, 2.5, 2.75 mg/kg D1D8 Q3W, respectively. In another cohort, 18 and 13 patients received iza-bren in combination with osimertinib at 4.0, 4.5 mg/kg D1 Q3W. Across both cohorts, osimertinib was administered at 80mg on a QD cycle.

Trial Status. This study was initiated in July 2023 in China and is expected to be completed in 2027 in terms of reaching primary endpoints. As of the data cut-off date on June 30, 2025, a total of 154 patients had been enrolled in this trial.

Efficacy Data. Iza-bren in combination with osimertinib demonstrated an encouraging preliminary antitumor activity. As of the data cut-off date (June 30, 2025), efficacy results from all 154 patients demonstrated that the combination of iza-bren and osimertinib achieved an overall ORR of 84.4%, a cORR of 80.5%, and an mPFS not reached with median follow-up for PFS of 12.7 months. The 12-month PFS rate was 86.5%, and the 12-month OS rate was 95.9%. The following table sets forth the efficacy data of subjects in different cohorts.

		D1D8Q3W			D1Q3W	
	Total	**2.2 mg/kg**	**2.5 mg/kg**	**2.75 mg/kg**	**4.0 mg/kg**	**4.5 mg/kg**
	(N=154)	*(N=41)*	*(N=40)*	*(N=42)*	*(N=18)*	*(N=13)*
BOR, n (%)						
PR	130 (84.4)	32 (78.0)	40 (100)	33 (78.6)	14 (77.8)	11 (84.6)
Confirmed PR	124 (80.5)	30 (73.2)	38 (95.0)	32 (76.2)	14 (77.8)	10 (76.9)
PR pending confirmation[(1)]	5 (3.2)	2 (4.9)	2 (5.0)	0	0	1 (7.7)
SD	19 (12.3)	7 (17.1)	0	7 (16.7)	3 (16.7)	2 (15.4)
PD	0	0	0	0	0	0
NE[(2)]	5 (3.2)	2 (4.9)	0	2 (4.8)	1 (5.6)	0
ORR, % (95%CI)	84.4 (77.7, 89.8)	78.0 (62.4, 89.4)	100 (91.2, 100.0)	78.6 (63.2, 89.7)	77.8 (52.4, 93.6)	84.6 (54.6, 98.1)
cORR, % (95%CI)	80.5 (73.4, 86.5)	73.2 (57.1, 85.8)	95.0 (83.1, 99.4)	76.2 (60.5, 87.9)	77.8 (52.4, 93.6)	76.9 (46.2, 95.0)
Median FU for PFS, mo (95%CI)	12.7 (12.5, 15.0)	15.2 (15.0, 15.2)	12.5 (12.4, 12.5)	15.1 (12.6, 17.9)	15.1 (11.0, 17.9)	13.1 (12.4, 15.2)
12-mo PFS rate, % (95%CI)	86.5 (79.7, 91.2)	86.2 (70.0, 94.0)	92.1 (77.5, 97.4)	81.8 (65.5, 90.9)	80.7 (51.1, 93.4)	92.3 (56.6, 98.9)
Median FU for OS, mo (95%CI)	15.0 (14.2, 15.5)	15.8 (15.4, 17.4)	12.8 (12.5, 13.1)	16.7 (15.3, 18.0)	17.2 (13.2, 17.9)	14.7 (13.1, 15.2)
12-mo OS rate, % (95% CI)	95.9 (91.2, 98.2)	94.9 (81.0, 98.7)	94.8 (80.7, 98.7)	97.6 (84.3, 99.7)	100.0 (100.0, 100.0)	92.3 (56.6, 98.9)

Notes: (1) Refers to patients still on study with tumor assessment of PR and not reach to the next time point of tumor assessment; (2) Including patients without post-baseline tumor assessment.

The D1D8 Q3W cohort achieved an overall ORR of 85.4%, with 95.9% of patients experiencing tumor shrinkage. The median percentage reduction in tumor size was -53.8% (range: -87.4% to -15.6%). Notably, among 40 evaluable patients who received iza-bren at 2.5 mg/kg D1D8 Q3W in combination with osimertinib as a first-line therapy, the combination achieved an ORR of 100%, a cORR of 95% (with two partial responses pending confirmation), and a DCR of 100% as of June 30, 2025. All patients in this cohort experienced tumor shrinkage, with a median reduction of -56.7% (range: -87.4% to -34.4%). At a median follow-up of 12.5 months, the 12-month PFS rate was 92.1% and the 12-month OS rate was 94.8%, while neither DoR nor mPFS had been reached.

Safety Data. As of the data cut-off date (June 30, 2025), iza-bren showed manageable safety profile in the treatment of NSCLC in combination with osimertinib. Most of the common adverse events were hematological toxicities, including anemia, neutropenia, leukopenia, and thrombocytopenia. Other TRAEs included nausea, stomatitis, decreased appetite, vomiting, diarrhea, asthenia, increased AST, increased ALT, hypokalemia, hypoalbuminemia, decreased weight, rash, and alopecia. Among the patients in the study, the incidence of TRAEs leading to treatment discontinuation was low. Two cases of ILD were reported, including one in Grade 2 and one in Grade 3. No new safety signals were identified.

Phase I Global Clinical Trial of Iza-bren as Monotherapy for NSCLC and Other Solid Tumors (NCT05983432)

This is a global, multi-center, Phase I study to evaluate the safety, tolerability, PK, and initial efficacy of iza-bren in participants with metastatic or unresectable NSCLC and other solid tumors. The primary endpoint is safety, and the secondary endpoints include PK, ORR, DCR, DoR, time to response, PFS, and OS.

Trial Design. Eligible subjects in this study must have locally advanced or metastatic NSCLC or other solid tumors, with measurable disease as defined by RECIST v1.1 and an ECOG performance status of 0 or 1. As of July 23, 2025 (the data cut-off date), a total of 107 subjects were enrolled in the dose escalation phase, who were assigned to two cohorts receiving iza-bren under different dosing schedules: Cohort A included 65 subjects, receiving iza-bren at 1.5, 2.0, 2.5, and 3.0 mg/kg D1D8 Q3W, respectively; Cohort B included 42 subjects, receiving iza-bren at 3.0, 4.0, and 4.5 mg/kg D1 Q3W, respectively. In the expansion phase, subjects are dosed at 1.5, 2.0, and 2.5 mg/kg D1D8 Q3W, respectively.

Trial Status. This study was initiated in August 2023 in the U.S. The Phase Ia stage was completed in January 2025 and the Phase Ib stage is currently ongoing. We expect the primary endpoints will be reached in 2026.

Efficacy Data. Iza-bren has demonstrated encouraging efficacy in heavily pre-treated patients in this trial. As of July 23, 2025, in Cohort A consisting of 63 eligible intent-to-treat population receiving iza-bren D1D8 Q3W, ORR was 38.1%, cORR was 34.9%, mPFS was 4.5 months and median follow-up for OS was 8.3 months. An enhanced efficacy profile was observed among the 20 patients treated at 2.5 mg/kg D1D8 Q3W, with an ORR and cORR of 55.0%, mPFS of 5.4 months and median follow-up for OS of 8.5 months. The following table sets forth the efficacy data in the D1D8 Q3W cohort.

D1D8Q3W	Total (N = 63)	1.5 mg/kg (N = 20)	2.0 mg/kg (N = 20)	2.5 mg/kg (N = 20)	3.0 mg/kg (N = 3)
Median (range) LoT	3 (1-10)	3 (1-10)	3 (1-6)	**2 (1-9)**	2 (1-3)
BOR, n					
CR	1	0	1	**0**	0
Confirmed CR	1	0	1	**0**	0
PR	23	4	6	**11**	2
Confirmed PR	21	4	4	**11**	2
SD	15	6	5	**4**	0
PD	15	6	5	**3**	1
NE	9	4	3	**2**	0
ORR, % (95%CI)	38.1 (26.1, 51.2)	20.0 (5.7, 43.7)	35.0 (15.4, 59.2)	**55.0 (31.5, 76.9)**	66.7 (9.4, 99.2)
cORR, % (95%CI)	34.9 (23.3, 48.0)	20.0 (5.7, 43.7)	25.0 (8.7, 49.1)	**55.0 (31.5, 76.9)**	66.7 (9.4, 99.2)
mPFS, mo (95%CI)	4.5 (3.4, 5.6)	3.4 (1.4, 5.4)	6.7 (1.2, 8.1)	**5.4 (3.8, 11.1)**	5.4 (1.4, NR)
Median FU for OS	8.3 (7.2, 9.1)	8.8 (4.3, 11.3)	7.7 (5.4, 9.6)	**8.5 (5.8, 9.3)**	10.2 (NR, NR)

Notably, potent efficacy was observed in the NSCLC subgroup regardless of EGFR mutation status. Among the EGFRmut NSCLC patients, ORR and cORR reached 30.0%, and mPFS was 5.4 months. Among the EGFRwt NSCLC patients, ORR and cORR reached 75.0%, and mPFS has not been reached. The group of patients with NSCLC receiving iza-bren at 2.5 mg/kg D1D8 Q3W, consistent with the overall population in Cohort A, demonstrated improved efficacy. The following tables set forth the efficacy data in patients with EGFRmut NSCLC and EGFRwt NSCLC receiving iza-bren D1D8 Q3W cohort, respectively.

NSCLC EGFRmt D1D8Q3W	Total (N = 22)	1.5 mg/kg (N = 5)	2.0 mg/kg (N = 6)	2.5 mg/kg (N = 10)	3.0 mg/kg (N = 1)
Median (range) LoT	3 (1-9)	2 (1-4)	3 (1-5)	**3 (1-9)**	1 (1-1)
Prior Ami*, n (%)	9 (40.9)	2 (40.0)	3 (50.0)	4 (40.0)	0
Baseline CNS mets, n (%)	5 (22.7)	1 (20.0)	1 (16.7)	3 (30.0)	0
BOR, n (%)					
PR	5	1	0	**3**	1
Confirmed PR	5	1	0	**3**	1
SD	5	1	1	**3**	0
ORR, % (95%CI)	22.7 (7.8, 45.4)	20.0 (0.5, 71.6)	0 (0.0, 45.9)	**30.0 (6.7, 65.2)**	100 (2.5, 100.0)
cORR, % (95%CI)	22.7 (7.8, 45.4)	20.0 (0.5, 71.6)	0 (0.0, 45.9)	**30.0 (6.7, 65.2)**	100 (2.5, 100.0)
mPFS, mo (95%CI)	3.2 (1.2, 8.1)	1.3 (1.2, NR)	1.3 (1.2, NR)	**5.4 (0.5, NR)**	NR (NR, NR)

NSCLC EGFRwt D1D8Q3W	Total (N = 20)	1.5 mg/kg (N = 8)	2.0 mg/kg (N = 8)	2.5 mg/kg (N = 4)
Median (range) LoT	2 (1-9)	3 (1-9)	2 (1-5)	**2 (1-3)**
Squamous, n (%)	6 (30.0)	4 (50.0)	1 (12.5)	**1 (25.0)**
BOR, n (%)				
PR	9	3	3	**3**
Confirmed PR	8	3	2	**3**
SD	5	1	3	**1**
ORR, % (95%CI)	45.0 (23.1, 68.5)	37.5 (8.5, 75.5)	37.5 (8.5, 75.5)	**75.0 (19.4, 99.4)**
cORR, % (95%CI)	40.0 (19.1, 63.9)	37.5 (8.5, 75.5)	25.0 (3.2, 65.1)	**75.0 (19.4, 99.4)**
mPFS, mo (95%CI)	6.9 (2.8, 10.0)	5.4 (1.5, NR)	6.9 (0.4, NR)	**NR (4.5, NR)**

Note: * Patients with prior amivantamab, amivantamab + platinum-based chemotherapy, amivantamab + lazertinib, or amivantamab with any other combinations.

Safety Data. Iza-bren exhibited a manageable safety profile in heavily pre-treated patients across multiple tumor types. As of July 23, 2025, the most frequent Grade ≥3 TRAEs in the iza-bren arm were mainly hematologic and were effectively managed by standard medical measures. No ILD was observed, and no new safety signals were observed.

NPC, ESCC, BC and Beyond

Phase I Clinical Trial of Iza-bren as Monotherapy for Locally Advanced or Metastatic BC and Other Solid Tumors (NCT05470348)

This is an open-label, Phase I clinical trial to evaluate the safety, tolerability, pharmacokinetic characteristics, and initial efficacy in patients with locally advanced or metastatic BC and other solid tumors. The primary endpoints for this trial are DLT, MTD or maximum administered dose ("**MAD**"), and RP2D. The secondary endpoints are TEAEs, PK parameters, ORR, DCR, and DoR. The exploratory endpoints include PFS, OS, biomarker, and NAb.

Trial Design. This study includes patients with locally advanced or metastatic BC and other solid tumors who have a performance status score of 0 or 1 according to the ECOG. These patients must have at least one measurable lesion per RECIST v1.1 and must have been treated with standard therapy. With reference to the dose-escalation study of iza-bren for locally advanced or metastatic solid tumors (NCT05194982), most patients in this study received iza-bren at a dosage of 2.5 mg/kg D1D8 Q3W.

Trial Status. This study was initiated in China in August 2022 and is expected to be completed in 2026 in terms of reaching primary endpoints. As of the data cut-off date (September 30, 2024), a total of 162 patients with BC had been enrolled at 2.5 mg/kg D1D8 Q3W in this trial. The Phase Ia was completed in December 2022. The Phase Ib (dose expansion) stage for TNBC was completed in December 2023 in terms of reaching primary endpoints.

Efficacy Data. We conducted the efficacy analysis in this study based on the intent-to-treat population. We enrolled 162 patients in this study as of the data cut-off date (September 30, 2024), with the median follow-up duration of 11.6 months. One patient with HER2+ BC was excluded from the analysis due to insufficient follow-up data.

As of the data cut-off date (September 30, 2024), 44 response-evaluable patients with TNBC administered with iza-bren achieved an overall ORR and cORR of 34.1%, DCR of 81.8%, mPFS of 5.8 months, and mDoR of 11.5 months; 77 response-evaluable patients with HR+/HER2- BC administered with iza-bren achieved an overall ORR of 46.8%, cORR of 37.7%, DCR of 79.2%, mPFS of 7.0 months, and mDoR of 7.4 months; 40 response-evaluable patients with HER2+ BC administered with iza-bren achieved an overall ORR and cORR of 47.5%, DCR of 80.0%, mPFS of 7.0 months, and mDoR of 7.4 months. Iza-bren showed more encouraging signals of efficacy in TNBC and HR+/HER2- BC patients who had received one or two prior lines of chemotherapy. In 26 TNBC patients with one or two previous lines of chemotherapy, the ORR and cORR were both 50.0%, and mPFS was 6.9 months. In 46 HR+/HER2- BC patients with one or two previous lines of chemotherapy, the ORR was 54.3%, cORR was 45.7%, DCR was 82.6%, and mPFS was 8.3 months.

Safety Data. As of the data cut-off date (September 30, 2024), iza-bren exhibited a manageable safety profile. No ILD was observed in all 162 enrolled patients, and the most common TRAEs were anemia, leukopenia, neutropenia and thrombocytopenia.

Phase I Clinical Trial of Iza-bren as Monotherapy for Locally Advanced or Metastatic GIC and Other Solid Tumors (NCT05262491)

This is an open-label, Phase I study designed to evaluate iza-bren safety, tolerability, pharmacokinetic characteristics, and preliminary efficacy in patients with locally advanced or metastatic GIC and other solid tumors, including ESCC and BTC. The primary endpoints of the study are DLT, MTD, and RP2D, and the secondary endpoints are TEAE, PK parameters, ORR, DCR, and DoR. Exploratory endpoints are PFS, OS, biomarker, and nAb.

Trial Design. This study includes patients with locally advanced or metastatic GIC and other solid tumors who have a performance status score of 0 or 1 according to the ECOG and have measurable disease per RECIST v1.1. These patients must have been previously treated with at least one line of therapy. This trial consists of Phase Ia (dose escalation) and Phase Ib (dose expansion) stages. In the dose-expansion phase, subjects with different tumor types were assigned into three treatment arms based on dosing, all of which were performed on a D1D8 Q3W regimen.

Trial Status. This study was initiated in February 2022 in China and is expected to be completed in 2026 in terms of reaching primary endpoints. The Phase Ia was completed in July 2022. The Phase Ib (dose expansion) stage for ESCC was completed in November 2023 in terms reaching primary endpoints.

For details regarding key clinical trial results for ESCC, see "— Phase III Clinical Trial of Iza-bren as Monotherapy for Recurrent or Metastatic ESCC (NCT06304974)." Below is a summary of key clinical trial results for BTC in the Phase I trial. As of data cut-off date (June 30, 2024), 44 patients with BTC were enrolled. Among these subjects, 31, three and 10 patients received iza-bren at 2.5 mg/kg, 3.0 mg/kg, and 3.5 mg/kg, respectively.

Efficacy Data. As of the data cut-off date (June 30, 2024), there were 36 response-evaluable patients with locally advanced or metastatic BTC administered with iza-bren, with an overall ORR of 38.9%, cORR of 22.2%, DCR of 88.9%, mPFS of 4.2 months, and mDoR of 5.9 months.

Safety Data. As of the data cut-off date (June 30, 2024), iza-bren showed manageable safety profile in the treatment of BTC. The most common TRAEs were hematological toxicities. No cases of ILD were observed, and no new safety signals were identified during the study.

Phase III Clinical Trial of Iza-bren as Monotherapy for Recurrent or Metastatic NPC (NCT06118333)

This is a Phase III, randomized, open-label, multicenter study to evaluate the efficacy and safety of iza-bren in patients with recurrent or metastatic NPC who had failed at least two lines of platinum-based chemotherapy after receiving PD-1/PD-L1 monoclonal antibody as the last line of therapy. This study was conducted at 55 study centers in China. The primary endpoints include ORR by blinded independent central review (BICR) and OS. The secondary endpoints include PFS by BICR and investigator assessment (INV), ORR by INV, DoR, DCR, safety, PK and immunogenicity.

Trial Design. Eligible subjects in this study were required to have histologically or cytologically confirmed recurrent or metastatic NPC with at least one measurable lesion as defined by RECIST v1.1. They must have experienced disease progression after at least two lines of systemic chemotherapy including at least one platinum-based chemotherapy and a PD-(L)1 inhibitor and have an ECOG performance status of 0 or 1. As of March 30, 2025, a total of 386 patients were randomized into two groups, including 191 assigned to the iza-bren arm and 195 assigned to the comparator arm. In the iza-bren arm, patients received iza-bren at 2.5 mg/kg D1D8 Q3W. In the comparator arm, patients were treated with chemotherapy, including capecitabine at 1,000 mg/m^2 twice a day from days 1 to 14 Q3W, gemcitabine at 1,000 mg/m^2 on D1D8 Q3W, and docetaxel at 75 mg/m^2 Q3W.

Trial Status. This study was initiated in December 2023 in China and met the ORR primary endpoint in March 2025. Based on these data, we submitted an NDA for NPC in July 2025. This NDA was accepted for filing and has been formally admitted into the Priority Review Program by the CDE in September 2025. In June 2026, we received the NDA conditional approval from the NMPA. As of the Latest Practicable Date, the follow-up for OS, the other primary endpoint, remained ongoing.

Efficacy Data. Iza-bren achieved a statistically significant and clinically meaningful improvement in ORR as assessed by BICR, compared with chemotherapy, in heavily pretreated patients with recurrent or metastatic NPC. We conducted an interim analysis of this Phase III clinical trial in the first 234 randomized patients who had at least six months of follow-up per protocol as of March 30, 2025, including 119 patients in the iza-bren arm and 115 patients in the chemotherapy arm. In the iza-bren arm, 74.8% of patients (89/119) had tumor shrinkage and the median shrinkage was -45.5% (range: -84.4% to -1.3%), while in the chemotherapy arm, only 58.3% of patients (67/115) had tumor shrinkage and the median shrinkage was -33.6% (range: -75.0% to -1.0%). In the iza-bren arm, the ORR and DCR reached 54.6% and 82.4%, respectively, significantly higher than that of the chemotherapy arm at 27.0% and 69.6%, respectively. The odds ratio of ORR between the iza-bren and chemotherapy arms, with p-value less than 0.0001, indicates that patients in the iza-bren arm were 3.3 times more likely to achieve an objective response compared to those in the chemotherapy arm, a difference that was statistically significant.

Iza-bren also demonstrated a longer mDoR of 8.5 months, compared with 4.8 months observed in the chemotherapy arm. The hazard ratio between these two arms is 0.43, indicating that patients in the treatment arm had a 57% lower risk of disease progression or loss of response compared with those in the control arm. All subgroups demonstrated a consistent ORR benefit with iza-bren, compared to chemotherapy.

In addition, we evaluated the BICR-assessed PFS in the intention-to-treat population, which included all randomized subjects, regardless of whether they completed the treatment or adhered to the study protocol. The mPFS of the iza-bren arm was 8.38 months, significantly longer than 4.34 months in the chemotherapy arm. The hazard ratio between these two arms is 0.44, indicating that patients in the iza-bren arm had a 56% lower risk of disease progression or death compared with those in the chemotherapy arm. Accordingly, iza-bren showed a clinically meaningful improvement in PFS by BICR. The subgroups also consistently showed a benefit with iza-bren over chemotherapy in terms of BICR-assessed PFS.

Safety Data. Iza-bren exhibited manageable safety profile, and no new safety signals were identified. The rate of treatment discontinuation due to TRAEs in the iza-bren arm was low (2.6%), compared to the chemotherapy arm (3.2%). The most frequent Grade ≥3 TRAEs in the iza-bren arm were mainly hematologic and were effectively managed using standard supportive care. The majority of non-hematologic TRAEs were Grade 1 or 2. While two patients (1.1%) in the chemotherapy arm experienced Grade 3 ILD, the two cases (1.1%) of ILD observed in the iza-bren arm were Grade 2.

Phase III Clinical Trial of Iza-bren as Monotherapy for Recurrent or Metastatic ESCC (NCT06304974)

This is a Phase III, multicenter, randomized, open-label study to evaluate the efficacy and safety of iza-bren versus chemotherapy in patients with recurrent or metastatic ESCC who had progressed after first-line treatment with a PD-1/PD-L1 inhibitor plus platinum-based chemotherapy. The dual primary endpoints are PFS by BICR and OS. The secondary endpoints include ORR by BICR, PFS by INV, DCR, DoR, safety, PK and immunogenicity.

Trial Design. Eligible subjects in this study were required to have histologically or cytologically confirmed recurrent or metastatic ESCC with at least one measurable lesion as defined by RECIST v1.1. They must have progressed after first-line treatment with a PD-1/PD-L1 inhibitor

plus platinum-based chemotherapy and have an ECOG performance status of 0 or 1. Patients were stratified by baseline ECOG PS (0 vs. 1) and definitive treatment (surgery or radiotherapy for the primary tumor, yes vs. no). The planned enrollment was 488 subjects. A total of 497 patients were randomized 1:1 to receive either iza-bren at 2.5 mg/kg D1D8 Q3W (N=249) or physician's choice of chemotherapy (N=248), consisting of irinotecan (125 mg/m^2 D1D8 Q3W), paclitaxel (175 mg/m^2 D1 Q3W) or docetaxel (75 mg/m^2 D1 Q3W). Treatment continued until disease progression per RECIST v1.1 or intolerable toxicity.

Trial Status. This study was initiated in March 2024 in China, and the primary endpoints were reached in October 2025. Due to its remarkable efficacy, iza-bren as monotherapy for second-line ESCC was designated as a breakthrough therapy by the CDE in October 2024. We submitted an NDA for iza-bren for the treatment of ESCC in December 2025 and received the approval from the NMPA in July 2026.

Efficacy Data. We conducted a pre-specified interim analysis as of the data cut-off date (October 17, 2025). A total of 493 patients were included in the mITT population, comprising 249 patients treated with iza-bren and 244 patients treated with chemotherapy. The median duration of follow-up for PFS was 5.8 months and the median duration of follow-up for OS was 7.8 months.

The study met both dual primary endpoints of PFS by BICR and OS at the pre-specified interim analysis. Iza-bren demonstrated a statistically significant and clinically meaningful improvement in PFS by BICR compared with chemotherapy. The median PFS was 4.17 months (95% CI: 3.61, 4.53) in the iza-bren arm versus 1.97 months (95% CI: 1.61, 2.73) in the chemotherapy arm (HR=0.50, 95% CI: 0.40–0.63; one-sided P<0.0001). The 6-month PFS rate was 32.7% in the iza-bren arm versus 14.7% in the chemotherapy arm, and the 9-month PFS rate was 13.7% versus 2.6%.

Iza-bren also demonstrated a statistically significant and clinically meaningful improvement in OS compared with chemotherapy. The median OS was 9.79 months (95% CI: 7.89, 11.01) in the iza-bren arm versus 7.20 months (95% CI: 6.18, 8.25) in the chemotherapy arm (HR=0.64, 95% CI: 0.49–0.83; one-sided P=0.0004). The 6-month OS rate was 75.2% in the iza-bren arm versus 58.4%, and the 12-month OS rate was 34.8% versus 22.5%.

The ORR by BICR was 35.3% (95% CI: 29.4, 41.6) in the iza-bren arm versus 13.1% (95% CI: 9.1, 18.0) in the chemotherapy arm. The confirmed ORR by BICR was 27.7% (95% CI: 22.2, 33.7) versus 9.4% (95% CI: 6.1, 13.8), with an odds ratio of 3.6 (95% CI: 2.2, 6.1). In the iza-bren arm, 0.8% of patients achieved a complete response ("**CR**") and 26.9% achieved a confirmed PR. The DCR was 74.3% (95% CI: 68.4, 79.6) versus 45.5% (95% CI: 39.1, 52.0). The median DoR was 5.7 months (95% CI: 4.1, 6.9) in the iza-bren arm versus 5.6 months (95% CI: 4.2, 6.8). In the iza-bren arm, 65.9% of patients (164/249) experienced tumor shrinkage, with a median shrinkage of -31.5% (range: -100.0% to -0.7%).

Consistent PFS benefit was observed across all pre-specified subgroups, including by age, ECOG PS, smoking status, disease staging, number of organ metastases and definitive treatment status. More patients in the chemotherapy arm (53.7%) received at least one subsequent anti-cancer therapy compared with the iza-bren arm (37.3%).

Safety Data. Grade ≥3 TRAEs were reported in 85.1% of patients in the iza-bren arm versus 60.2% in the chemotherapy arm, predominantly hematologic in nature and clinically manageable. The rate of TRAEs leading to treatment discontinuation was low (2.0% vs. 3.3%). TRAEs leading to death occurred in 3 patients (1.2%) in the iza-bren arm and 4 patients (1.6%) in the chemotherapy arm. The rates of all-grade and Grade ≥3 ILD were 1.6% and 0.8%, respectively, in the iza-bren arm. No new safety signals were observed.

Phase III Clinical Trial of Iza-bren as Monotherapy for Unresectable Locally Advanced or Metastatic TNBC (NCT06382142)

This is a Phase III, multicenter, randomized, open-label study to evaluate the efficacy and safety of iza-bren versus physician's choice of chemotherapy in patients with unresectable locally advanced or metastatic TNBC who had progressed after one to two prior lines of systemic therapy for advanced disease, including prior taxanes. The dual primary endpoints are PFS by BICR and OS. The secondary endpoints include ORR by BICR, PFS by INV, DCR, DoR, safety, PK and immunogenicity.

Trial Design. Eligible subjects in this study were required to have histologically or cytologically confirmed unresectable locally advanced or metastatic TNBC with at least one measurable lesion as defined by RECIST v1.1. They must have progressed after one to two prior lines of systemic therapy for advanced disease, including prior taxanes, and have an ECOG performance status of 0 or 1. Patients were stratified by prior anti-PD(L)-1 therapy (yes vs. no), previous lines of chemotherapy (1 line vs. 2 lines), and HER2 expression (immunohistochemistry ("**IHC**") 0 vs. IHC 1+/2+ ISH−). A total of 418 patients were randomized 1:1 to receive either iza-bren at 2.5 mg/kg D1D8 Q3W (N=211) or physician's choice of chemotherapy (N=207), consisting of eribulin (1.4 mg/m^2 D1D8 Q3W), capecitabine (1000–1250 mg/m^2 BID D1–14 Q3W), gemcitabine (1000 mg/m^2 D1D8 Q3W) or vinorelbine (25 mg/m^2 D1D8 Q3W). Treatment continued until disease progression per RECIST v1.1 or intolerable toxicity.

Trial Status. This study was initiated in June 2024, and the primary endpoints were reached in January 2026. We submitted an NDA for iza-bren for the treatment of TNBC to the NMPA in May 2026, which had been accepted for filing as of the Latest Practicable Date.

Efficacy Data. We conducted a pre-specified interim analysis as of the data cut-off date (January 13, 2026). A total of 412 patients were included in the modified intent-to-treat (mITT) population, comprising 207 patients treated with iza-bren and 205 patients treated with chemotherapy. The median duration of follow-up for PFS was 8.5 months and the median duration of follow-up for OS was 11.0 months.

The study met both dual primary endpoints of PFS by BICR and OS at the pre-specified interim analysis. Iza-bren demonstrated a statistically significant and clinically meaningful improvement in PFS by BICR compared with chemotherapy. The median PFS was 8.5 months (95% CI: 6.9, 9.8) in the iza-bren arm versus 3.1 months (95% CI: 2.7, 4.1) in the chemotherapy arm (HR=0.29, 95% CI: 0.22–0.38; one-sided P<0.0001). Iza-bren reduced the risk of disease progression or death by 71%. The 6-month PFS rate was 62.0% (95% CI: 54.3, 68.8) in the iza-bren arm versus 17.6% (95% CI: 12.0, 24.0) in the chemotherapy arm, and the 9-month PFS rate was 47.7% (95% CI: 39.4, 55.6) versus 7.7% (95% CI: 3.8, 13.4).

Iza-bren also demonstrated a statistically significant and clinically meaningful improvement in OS compared with chemotherapy. The median OS was 15.9 months (95% CI: 13.3, NR) in the iza-bren arm versus 12.5 months (95% CI: 11.4, NR) in the chemotherapy arm (HR=0.60, 95% CI: 0.42–0.85; one-sided P=0.0019). Iza-bren reduced the risk of death by 40%. The 9-month OS rate was 79.9% (95% CI: 73.1, 85.2) in the iza-bren arm versus 67.5% (95% CI: 58.7, 74.8), and the 12-month OS rate was 68.7% (95% CI: 61.0, 75.2) versus 53.5% (95% CI: 44.4, 61.7).

The confirmed ORR by BICR was 51.7% (95% CI: 44.7, 58.7) in the iza-bren arm versus 20.5% (95% CI: 15.2, 26.7) in the chemotherapy arm (odds ratio: 4.3, 95% CI: 2.8, 6.7). In the iza-bren arm, 3.9% of patients achieved a complete response and 47.8% achieved a PR. The DCR was 83.1% versus 59.0%. The median DoR was 8.3 months (95% CI: 8.1, 11.0) in the iza-bren arm versus 4.0 months (95% CI: 2.9, 5.2) in the chemotherapy arm. In the iza-bren arm, 77.3% of patients (160/207) experienced tumor shrinkage, with a median shrinkage of -44.6% (range: -100.0% to -2.3%).

Notably, consistent and statistically significant PFS benefit was observed regardless of HER2 expression status. In HER2 IHC 0 patients, the median PFS was 8.3 months with iza-bren versus 2.6 months with chemotherapy (HR=0.28, 95% CI: 0.20–0.41; P<0.0001). In HER2-low patients (IHC 1+ or IHC 2+/ISH−), the median PFS was 9.7 months with iza-bren versus 4.1 months with chemotherapy (HR=0.32, 95% CI: 0.22–0.46; P<0.0001). Consistent PFS benefit was observed across all pre-specified subgroups, including by prior anti-PD(L)-1 therapy, number of previous chemotherapy lines, baseline liver metastasis status, ECOG performance status, and prior (neo)adjuvant chemotherapy.

More patients in the chemotherapy arm (63.4%) received at least one subsequent anti-cancer therapy compared with the iza-bren arm (38.6%). In the chemotherapy arm, 42.0% of patients received a subsequent ADC. Iza-bren demonstrated a statistically significant improvement in OS despite more patients receiving subsequent therapies, including ADCs, in the chemotherapy arm.

Safety Data. Grade ≥3 TEAEs were reported in 88.9% of patients in the iza-bren arm versus 62.9% in the chemotherapy arm, predominantly hematologic in nature and effectively managed by standard supportive care. The rate of TEAEs leading to treatment discontinuation was low (1.9% vs. 0.5%). TEAEs leading to death occurred in 6 patients (2.9%) in the iza-bren arm and 2 patients (1.0%) in the chemotherapy arm. Per independent ILD adjudication committee, one (0.5%) case of Grade 2 ILD occurred in the iza-bren arm. No new safety signals were observed.

Phase II Clinical Trial of Iza-bren as Monotherapy for Locally Advanced or Metastatic UC (NCT05785039)

This is a Phase II clinical study to evaluate the safety, tolerability, PK and efficacy of iza-bren for injection in patients with multiple solid tumors such as locally advanced or metastatic UC. The primary endpoint for this trial is ORR by investigator's assessment, and the secondary endpoints are DCR, PFS, DoR and safety.

Trial Design. This study includes patients with locally advanced or metastatic UC who have a performance status score of 0 or 1 according to the ECOG and have measurable disease per RECIST v1.1. These patients must have failed standard therapy or have no feasible treatment available. During the trial, patients were assigned into three treatment arms based on dosing, all of which were performed on a 21-day cycle. As of the data cut-off date (June 30, 2024), 34 patients received iza-bren at 2.2 mg/kg D1D8 Q3W, four patients received iza-bren at 2.5 mg/kg D1D8 Q3W, and three were treated with iza-bren at 2.75 mg/kg D1D8 Q3W. Treatment continued until disease progression or the development of intolerable toxicity.

Trial Status. This study was initiated in April 2023 in China and is expected to be completed in 2026 in terms of reaching primary endpoints. As of June 30, 2024, a total of 41 patients had been enrolled in this trial. In light of the promising outcomes, we initiated a Phase III registrational trial for recurrent or metastatic UC (NCT06857175) in March 2025.

Efficacy Data. As of the data cut-off date (June 30, 2024), there were 27 response-evaluable patients with locally advanced or metastatic UC administered with iza-bren at 2.2 mg/kg dose level D1D8 Q3W. Findings showed that these 27 patients with a median of two prior treatment lines achieved the ORR of 40.7%, cORR of 33.3%, DCR of 96.3% and the 6-month DoR of 100%. The mDoR and mPFS have not been reached as of the data cut-off date.

The preliminary efficacy of iza-bren is particularly pronounced in patients with previously treated UC, with notable results observed in second-line treatment. 12 of the total evaluable patients have received one prior line of chemotherapy via platinum-based therapy or an ADC, showing an ORR of 75%, cORR of 75.0%, DCR of 100%, and 6-month DoR rate of 100%, after administered with iza-bren as of the data cut-off date. The mDoR and mPFS had not been reached as of the data cut-off date.

Safety Data. As of the data cut-off date (June 30, 2024), iza-bren showed favorable safety profile at 2.2 mg/kg D1D8 Q3W in the treatment of UC. The most common TRAEs were hematological toxicities, which were manageable, and the non-hematological toxicities were mostly Grade 1 or 2. No drug-related death was observed. The incidence and severity of toxicities related to EGFR and HER3 targeting were relatively low. No cases of ILD were observed, and no new safety signals were identified during the study.

Phase Ib/II and Phase II Clinical Trials of Iza-bren as Monotherapy for OC (NCT05803018, NCT05990803)

We evaluate the safety, efficacy, and PK profile of iza-bren as monotherapy in patients with recurrent or metastatic gynecologic cancers and other solid tumors in one Phase Ib/II study (NCT05803018) and one Phase II study (NCT05990803). In the Phase Ib study, the primary endpoint is RP2D, and the secondary endpoints include TEAE, ORR, DCR, DoR, PK and immunogenicity. In the Phase II study, the primary endpoint is ORR while the secondary endpoints include PFS, DCR, DoR, TEAE, PK and immunogenicity.

Trial Design. Eligible subjects in these studies must have recurrent or metastatic gynecological cancers confirmed by histopathology and/or cytology, with measurable disease as defined by RECIST v1.1 and an ECOG performance status of 0 or 1. They must have failed to standard therapy or without feasible standard treatment. All enrolled subjects were dosed on a D1D8 Q3W schedule, while divided into three cohorts receiving 2.0, 2.3, and 2.5 mg/kg iza-bren, respectively. As of July 31, 2025 (the data cut-off date), 96 patients with OC who have progressed on at least one line of platinum-based chemotherapy were enrolled and treated with iza-bren at 2.0 (N=10), 2.3 (N=60), 2.5 (N=26) mg/kg D1D8 Q3W.

Trial Status. The two clinical trials were initiated in June 2023 (NCT05803018) and November 2023 (NCT05990803) in China, respectively, and both are expected to be completed in 2026 in terms of reaching primary endpoints.

Efficacy Data. As of July 31, 2025, 81.3% of the total patients (78/96) had tumor shrinkage and the median shrinkage was -42.9% (range: -91.3% to -0.1%). In all population (N=96), ORR was 53.1%, cORR was 46.9%, mDoR was 8.5 months, mPFS was 7.0 months, median follow up for OS was 12.5 months, and mOS had not been reached.

As of July 31, 2025, data from the 2.3 mg/kg D1D8 Q3W cohort exhibited more compelling efficacy, with the cORR of 55.0%, mDoR of 8.5 months, and mPFS of 8.3 months. In this 2.3 mg/kg D1D8 Q3W cohort, a total of 49 patients (81.7%) had platinum-resistant OC, where the cORR was 49.0%, mDoR was 8.2 months, and mPFS was 7.0 months. In the remaining 11 patients with platinum sensitive OC, cORR was 81.8%, mDoR has not been reached, and mPFS was 14.0 months.

Safety Data. Iza-bren demonstrated a manageable safety profile in patients with OC who have progressed on at least one line of platinum-based chemotherapy. As of July 31, 2025, TRAEs occurred in all patients, and Grade ≥3 TRAEs occurred in 87.5% of patients. Most common Grade 3 and above AEs were hematologic toxicities, which were effectively managed with standard supportive care.

Clinical Development Plan

Our iza-bren is the world's first EGFR × HER3 bispecific ADC approved for commercialization. We are advancing the clinical development of iza-bren with the aim of making it a backbone treatment for a broad range of solid tumors. Our development strategy focuses on four key priorities outlined below:

- *Demonstrating pan-tumor efficacy*: We are evaluating iza-bren across more than 10 epithelial cancers where it has shown promising efficacy and manageable safety, with the goal of demonstrating broad applicability across multiple solid tumor indications.

- *Targeting large-market opportunities while leveraging near-term commercial and registrational milestones:* We focus our long-term development on major cancer types with immense market potential, such as NSCLC and BC. Concurrently, we are leveraging our advanced regulatory progress in early-to-market indications: we received NDA approvals for NPC and ESCC in June and July 2026, respectively, and our NDA submission for TNBC had been accepted by the NMPA as of the Latest Practicable Date. This dual-track strategy allows us to achieve rapid commercialization while establishing a robust foundation for broader market expansion.

- *Evaluating across modalities and treatment lines*: We are developing iza-bren as both monotherapy and in combination with immuno-oncology therapies, targeted therapies and chemotherapy. In 1L settings, we plan to evaluate iza-bren with PD-(L)1 therapies to potentially replace chemotherapy in indications where PD-(L)1-based combinations are standard of care, and with TKIs to potentially establish new standards in TKI-treated indications. We are also continuing development in late-line settings and advancing into neoadjuvant and adjuvant therapies.

- *Conducting global clinical trials to reach the worldwide market*: Under our global license and collaboration agreement with BMS, SystImmune and BMS have initiated, and plan to continue launching late-stage global studies of iza-bren globally across multiple solid tumors.

As of the Latest Practicable Date, we were conducting over 45 clinical trials for iza-bren in China and overseas. These include (i) 14 Phase III clinical trials of various cancers in China, including NSCLC, SCLC, BC, ESCC, NPC, UC and OC three of which had supported key regulatory milestones comprising conditional approval for NPC, approval for ESCC and acceptance for filing of the NDA for TNBC; (ii) three global pivotal Phase II/III registrational trials for TNBC, NSCLC and UC; (iii) two additional Phase II/III registrational trials in China; (iv) 21 Phase II trials; and (v) six Phase Ib or Phase I/II trials. In addition, a global Phase III clinical trial for EGFRmut NSCLC is expected to be initiated in September 2026.

Material Communications with Competent Authorities

China

Monotherapy. We received the IND approval from the NMPA in October 2021 for the initiation of iza-bren's first-in-human clinical trial in patients with locally advanced or metastatic solid tumors in China as monotherapy. Under the IND approval, we were permitted to conduct clinical evaluation of iza-bren across multiple types of solid tumors as monotherapy, while further advancement into Phase III or potentially registrational trials in China required subsequent formal communications with the CDE. We have subsequently initiated over 20 clinical trials to explore iza-bren's potential as monotherapy across a broad range of solid tumor indications, including NSCLC, SCLC, BC, GIC, NPC, UC, OC, HNSCC and gynecological malignancies, among others. As of the Latest Practicable Date, we received NDA approvals for NPC and ESCC, and our NDA submission for TNBC had been accepted by the NMPA.

- *NPC.* The NPC cohort of our Phase I trial in patients with locally advanced or metastatic solid tumors (NCT05194982) generated the foundational data supporting our clinical trials for NPC. We initiated this Phase I trial in November 2021. The Phase Ia (dose escalation) part was completed in September 2022, and the Phase Ib (dose expansion) stage for NPC cohort was completed in July 2023 in terms of reaching primary endpoints. Based on promising Phase I data from the NPC cohort as of July 2023, we

submitted a pre-Phase III communication request to the CDE in July 2023 to discuss the proposed Phase III trial design. The CDE agreed to our proposed pivotal trial design in October 2023, expressing no major concerns regarding the preliminary Phase I results or the proposed Phase III protocol.

We subsequently initiated our Phase III registrational trial for treating NPC in December 2023. In recognition of its outstanding efficacy, iza-bren monotherapy for the treatment of recurrent or metastatic NPC was granted breakthrough therapy designation by the CDE in April 2024. The ORR primary endpoint of the Phase III trial was achieved in March 2025. Based on these data, we submitted a pre-NDA communication request to the CDE in June 2025, and upon receiving confirmation, submitted our NDA application for NPC in July 2025. This NDA was formally included in the Priority Review Program by the CDE in September 2025. In June 2026, we obtained the NDA conditional approval. As of the Latest Practicable Date, the follow-up for OS, the other primary endpoint, remained ongoing.

- *ESCC.* The ESCC cohort of our Phase I trial in patients with locally advanced or metastatic gastrointestinal tumor and other solid tumors (NCT05262491) generated the foundational data supporting our clinical trials for ESCC. We initiated this Phase I trial in February 2022. The Phase Ia (dose escalation) stage was completed in July 2022, and the Phase Ib (dose expansion) stage for ESCC was completed in November 2023, in terms of reaching primary endpoints. Based on the ESCC cohort data from the Phase I trial as of November 2023, we submitted a pre-Phase III communication request to the CDE in December 2023. The CDE agreed to our proposed pivotal Phase III trial design in March 2024, expressing no major concerns regarding the preliminary Phase I results or the proposed Phase III protocol.

  We initiated this Phase III trial in March 2024. Iza-bren monotherapy for the second-line treatment of ESCC was granted breakthrough therapy designation by the CDE in October 2024. The dual primary endpoints (PFS and OS) of this Phase III trial were reached in October 2025. We submitted a pre-NDA communication request to the CDE in December 2025, and upon receiving confirmation, submitted our NDA application for ESCC in the same month. In July 2026, we received the NDA approval from the NMPA.

- *TNBC.* The TNBC cohort of our Phase I trial in patients with unresectable locally advanced or metastatic BC and other solid tumors (NCT05470348) generated the foundational data supporting our clinical trials for TNBC. We initiated this Phase I trial in August 2022. The Phase Ia (dose escalation) stage was completed in December 2022, and the Phase Ib (dose expansion) stage for TNBC was completed in December 2023 in terms of reaching primary endpoints. Based on the TNBC cohort data from the Phase I trial as of December 2023, we submitted a pre-Phase III communication request to the CDE in January 2024. In April 2024, the CDE expressed no major concerns on the preliminary results of TNBC cohort and no objection to our commencement of the Phase III trial. We subsequently initiated this Phase III registrational trial in June 2024, and the dual primary endpoints (PFS and OS) were reached in January 2026. We submitted a pre-NDA communication request to the CDE in March 2026, and upon receiving confirmation, submitted our NDA for TNBC in May 2026. As of the Latest Practicable Date, the NDA had been accepted for filing by the NMPA.

Combination therapies. Following the initial IND approval for iza-bren monotherapy in October 2021, we submitted and obtained separate IND approvals from the NMPA for multiple combination therapy regimens to support the expansion of iza-bren's clinical development program in combination settings. In March 2023, we received IND approvals for iza-bren in combination with SI-B003, our anti-PD-1/cytotoxic T lymphocyte-associated antigen-4 ("**CTLA-4**") bispecific antibody, across multiple tumor types including NSCLC, NPC, SCLC, HNSCC, BC, UC, gynecological cancers and GIC. In April 2023, we received IND approvals for iza-bren in

combination with osimertinib in NSCLC. In April 2024, we received IND approvals for iza-bren in combination with PD-(L)1 monoclonal antibodies in NSCLC, NPC, SCLC, HNSCC, TNBC, GIC and UC, and in April 2025, further IND approvals for the same combination across cervical/endometrial cancer, HCC, RCC and BTC. In 2025 and 2026, we received further IND approvals for iza-bren in combination with TKI-based regimens for cervical/endometrial cancer, HCC, RCC and BTC, as well as for iza-bren in combination with abiraterone and/or olaparib for CRPC. These IND approvals have established the regulatory foundation for iza-bren's extensive Phase II combination therapy program, which is evaluating iza-bren in combination with ICIs, TKIs and other targeted agents across more than 10 solid tumor indications in both first-line and later-line settings.

Pre-Phase III communications. As of the Latest Practicable Date, iza-bren was being evaluated in 14 Phase III trials in China, encompassing both monotherapy and combination therapy across multiple indications, including NSCLC, SCLC, HR+/HER2- BC, TNBC, ESCC, BTC, UC and OC, as well as maintenance therapy setting. We also initiated two Phase II/III registrational trials evaluating iza-bren as perioperative therapy for EGFR-mutant NSCLC and in combination with a PD-1 inhibitor as first-line treatment for ESCC. All of these trials were initiated following formal communications with the CDE and their designs reflected feedback received from the CDE, in accordance with applicable regulatory requirements. The CDE did not raise any major concerns or objections to the proposed trial designs for any of these registrational or potentially registrational programs.

We did not receive any major concerns or objections from the above-mentioned regulatory authorities with respect to the clinical development plans for iza-bren.

The U.S.

SystImmune received the IND approval from the FDA in June 2023 for the initiation of iza-bren's first-in-human clinical trials in patients with metastatic or unresectable NSCLC and other solid tumors in the U.S. as monotherapy. We initiated the Phase I trial in August 2023. Following the execution of our agreement with BMS in December 2023, the FDA approved the INDs held by BMS for four trials between September 2024 and July 2025. These include one Phase I/IIa trial evaluating iza-bren combinations in advanced solid tumors (NCT06618287) and three Phase II/III trials across EGFR-mutant NSCLC (NCT07100080), TNBC and ER-low/HER2-negative BC (NCT06926868), and UC (NCT07106762). As of the Latest Practicable Date, all the trials were ongoing. In addition, following communications with the FDA, a protocol for a proposed global Phase III trial evaluating iza-bren in combination with osimertinib as first-line treatment for EGFR-mutant NSCLC was submitted to the FDA in June 2026. As of the Latest Practicable Date, the FDA did not raise major concerns or objections regarding the proposed design of this Phase III trial. The trial is expected to be initiated in September 2026. BMS and SystImmune will continue to maintain close communications with competent authorities at key milestones of iza-bren's clinical development.

License and Collaboration Agreement with Bristol-Myers Squibb Company

For details, see "— License and Collaboration Agreement with Bristol-Myers Squibb Company."

IZA-BREN MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

T-Bren (HER2 ADC), Our Core Product

Overview

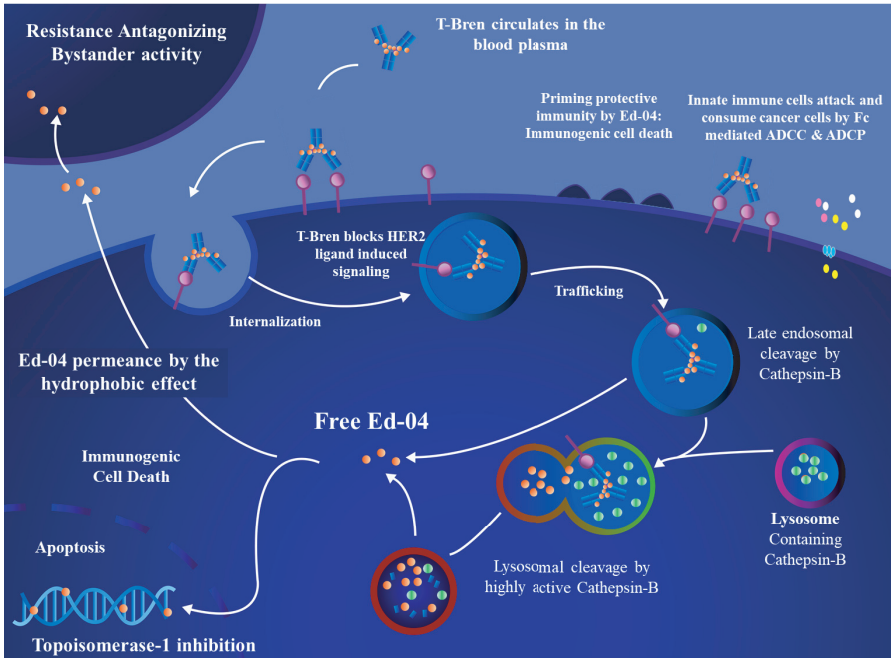
T-Bren is an innovative HER2-specific ADC with best-in-class potential. As a next-generation candidate in the HER2 ADC industry, T-Bren has validated its broad development potential in multiple HER2-expressing solid tumors, including NSCLC, BC, UC, GIC, gynecological cancers and digestive tract tumors. It is currently being evaluated as a single agent and in combination settings in 18 clinical trials in China and overseas, including eight Phase III and one Phase II/III registrational trials. It is the second Core Product generated from our HIRE-ADC platform to enter Phase III clinical development, demonstrating the repeatable productivity of our mature ADC discovery and development engine beyond iza-bren.

Mechanism of Action

HER2 is a transmembrane receptor tyrosine kinase belonging to the ErbB family, which also includes HER1 (EGFR), HER3, and human epidermal growth factor receptor 4 ("**HER4**"). Unlike the other family members, HER2 does not bind EGF-like ligands directly; instead, it activates downstream signaling by forming heterodimers with other ErbB receptors, regulating cell proliferation and survival. HER2 is overexpressed in various cancers, including BC, GC, lung cancer, and OC. Studies indicate that approximately 15-30% of BC patients exhibit HER2 gene amplification and overexpression.

T-Bren is engineered by conjugating a humanized HER2 antibody, trastuzumab, to our novel Topo1 inhibitor Ed-04 via a cleavable linker at a DAR of 8. Upon binding to HER2 on tumor cells, T-Bren is internalized and releases Ed-04 in the lysosomes, inducing cell death. In addition, the antibody component inhibits HER2 downstream signaling, while the Fc portion mediates antibody-dependent cell-mediated cytotoxicity ("**ADCC**"), together enhancing anti-tumor activity.

Mechanism of Action of T-Bren



Competitive Advantages

Novel ADC design with best-in-class potential. T-Bren incorporates our proprietary Topo1 inhibitor Ed-04 and a cleavable, highly stable linker designed to improve hydrophilicity and reduce aggregation, supporting potent antitumor activity with a manageable safety profile.

Superior preclinical efficacy versus marketed HER2 ADCs. In CDX tumor models, T-Bren demonstrated enhanced tumor suppression compared with certain marketed HER2 ADCs. Specifically, T-Bren showed superior anti-tumor activity versus both T-DM1 and Enhertu in a HER2+ BC model, exhibited greater efficacy than Enhertu in two HER2-low cancer models insensitive to T-DM1, and induced potent bystander effects in a mixed HER2+/HER2-low model with tumor inhibition superior to T-DM1 and comparable to Enhertu.

Encouraging clinical activity across HER2-expressing cancers. Building on the promising preclinical findings, T-Bren has demonstrated encouraging clinical activity and manageable safety in our clinical trials. Based on interim data as of July 31, 2025, T-Bren achieved an ORR of 86.7%, cORR of 82.2%, DCR of 97.8%, mPFS of 18.0 months, and mDoR of 19.4 months in 45 patients with HER2+ BC, with 12-month and 18-month OS rates of 93.1% and 85.5%, respectively. T-Bren also showed promising results in 60 patients with HR+/HER2- BC (ORR and cORR of 70.0%, DCR of 95.0%) and TNBC (ORR and cORR of 55.6%, DCR of 77.8%). Beyond BC, T-Bren achieved an ORR of 55.3% and cORR of 47.4% in 76 evaluable patients with previously treated HER2+ or HER2-low advanced GC/GEJ cancer. In a pooled analysis of two Phase II studies in HER2-expressing OC, T-Bren achieved a cORR of 52.5% and a nine-month PFS rate of 54.7%. These results highlight T-Bren's encouraging performance in heavily pretreated HER2-expressing cancers with manageable safety and tolerability.

Market Opportunity and Competition

For the market information of major proposed indications covered by T-Bren, see "Industry Overview — The Oncology Drug Market — Breast Cancer." As of the Latest Practicable Date, eight ADCs were approved for BC, among which five were HER2 ADCs. As of the same date, 17 ADC candidates were in Phase III or beyond clinical development for BC, among which 10 were HER2 ADC candidates.

Summary of Clinical Trial Data

The table below summarizes the trials for T-Bren in China:

Indication	Type of Therapy	Trial phase	Trial start date	(Expected) trial end year[(1)]
BC				
Locally advanced or metastatic HER2+ BC (NCT06316531)	Mono	Phase III	May 2024	(2026)
HER2-low recurrent/metastatic BC (NCT06957886)	Mono	Phase III	May 2025	(2027)
HER2+ BC (adjuvant) (NCT06830889)	Mono	Phase III	June 2025	(2031)
HER2+ recurrent or metastatic BC (first-line treatment) (NCT07518173)	Combo with pertuzumab	Phase III	April 2026	(2029)
HER2+ BC (neoadjuvant) (NCT06891833)	Combo with pertuzumab with or without taxane	Phase II/III	June 2025	(2028)

Indication	Type of Therapy	Trial phase	Trial start date	(Expected) trial end year[(1)]
Unresectable locally advanced or metastatic HER2+ BC (NCT06445400)	**Combo with pertuzumab; combo with pertuzumab and docetaxel**	**Phase II**	**June 2024**	**July 2025[(2)]**
Locally advanced or metastatic HER2+/HER2-low BC and other solid tumors (NCT05461768)	**Mono**	**Phase I**	**August 2022**	**(2026)[(3)]**
Other Solid Tumors				
HER2+ GC/GEJ cancer (NCT07152405)	Mono	Phase III	September 2025	(2027)
HER2mut NSCLC (NCT07178795)	Mono	Phase III	September 2025	(2027)
HER2-expressing locally advanced or metastatic BTC (NCT07606599)	Mono	Phase III	July 2026	(2028)
HER2-expressing platinum-resistant recurrent epithelial OC, fallopian tube cancer and primary peritoneal cancer (NCT07545460)	Mono	Phase III	2026Q3	(2028)
Locally advanced or metastatic HER2+ GC/GEJ cancer (NCT06423885)	Combo with PD-1 monoclonal antibody; combo with PD-1 monoclonal antibody and capecitabine	Phase II	December 2024	(2026)
Locally advanced or metastatic HER2-overexpressing non-squamous NSCLC (NCT07264816)	Combo with pembrolizumab	Phase II	February 2026	(2027)
Locally advanced or metastatic HER2-expressing urinary and GICs (NCT06031584)	**Mono**	**Phase Ib/II**	**January 2024**	**(2026)**
HER2-expressing gynecologic malignancies (NCT06131450)	Mono	Phase Ib/II	February 2024	(2026)
Locally advanced or metastatic HER2mut NSCLC (NCT06114511)	Mono	Phase Ib/II	April 2024	(2026)
Locally advanced or metastatic digestive tract tumors and other solid tumors (NCT05631964)	**Mono**	**Phase I**	**January 2023**	**(2026)**

Notes: (1) denotes estimated primary completion year; (2) primary endpoints of this trial were reached in July 2025; (3) primary endpoints of HER2+ BC and HER2-low BC cohorts were reached in December 2023 and November 2024, respectively.

The table below summarizes the trials for T-Bren outside China:

Indication	Type of Therapy	Trial phase	Trial start date	(Expected) trial end year[(1)]
HER2-expressing solid tumors (NCT06293898)	Mono	Phase I	February 2024	(2028)

Note: (1) denotes estimated primary completion year.

Key clinical trial results are summarized as below. The relevant trials are marked in bold in the table above. These selected trials established the preliminary clinical efficacy and safety of T-Bren for the relevant indications.

The First-in-Human Phase I Trial and Trial on BC

Phase I Clinical Trial of T-Bren as Monotherapy for Locally Advanced or Metastatic BC and Other Solid Tumors (NCT05461768)

This open-label and single-arm Phase I study is designed to evaluate T-Bren safety, tolerability, pharmacokinetic characteristics, and initial efficacy in patients with locally advanced or metastatic BC and other solid tumors. The primary endpoints are DLT, MTD and RP2D, and the secondary endpoints are TEAE, PK parameters, ORR, DCR, OS, PFS, and DoR. The exploratory endpoints are biomarker assessment and neutralizing antibodies.

Trial Design. This study includes patients with locally advanced or metastatic HER2-positive/low-expressing BC and other solid tumors who have a performance status score of 0 or 1 according to the ECOG, and have at least one measurable lesion per RECIST v1.1. These patients must have been previously treated with at least one line of therapy, have adequate organ and marrow function, and have either no brain metastases or stable brain metastases at screening. This Phase I consists of Phase Ia (dose escalation) and Phase Ib (dose expansion) stages. During dose-escalation stage, subjects received T-Bren in two different schedules, either D1 Q3W across nine dosage levels of 2.6 mg/kg, 3.2 mg/kg, 3.8 mg/kg, 4.4 mg/kg, 5.0 mg/kg, 5.6 mg/kg, 6.2 mg/kg, 6.8 mg/kg and 7.4 mg/kg, or a fixed dosage of 1.0 mg/kg D1D8 Q3W. In the dose-expansion phase, subjects were treated at doses of 3.8 mg/kg, 4.4 mg/kg and 5.0 mg/kg D1 Q3W.

Trial Status. This study was initiated in August 2022 in China and is expected to be completed in 2026 in terms of reaching primary endpoints. In November 2023, the Phase Ia (dose escalation) was completed. The Phase Ib (dose expansion) parts for HER2+ BC and HER2-low BC reached primary endpoints in December 2023 and November 2024, respectively.

The Phase Ib (dose expansion) part for GC/GEJ cohort reached primary endpoints in March 2025. For details regarding key clinical trial results for GC/GEJ, see "— Phase I and II Clinical Trials of T-Bren as Monotherapy for Previously Treated HER2+ Advanced GC or Gastroesophageal Junction Adenocarcinoma (GEJ)." Below is a summary of key clinical trial results for BC in the Phase I trial. As of July 31, 2025, a total of 199 BC patients had been treated with at least one dose of T-Bren.

Efficacy Data. As of the data cut-off date (July 31, 2025), there were 137 patients with locally advanced or metastatic HER2-expressing BC administered with T-Bren at 4.4 mg/kg dose level D1 Q3W. Among these patients, the ORR was 72.8%, cORR was 71.3%, mDoR was 13.9 months, and mPFS was 14.1 months. T-Bren also demonstrated promising efficacy across various BC subtypes, especially in the HER2+ BC subgroup, at the 4.4 mg/kg D1 Q3W dose level: In 45 patients with HER2+ BC, the ORR was 86.7%, cORR was 82.2%, DCR was 97.8%, mDoR was 19.4 months,

mPFS was 18.0 months, and the 12 and 18-month OS rate was 93.1% and 85.5%, respectively. In 60 patients with HR+/HER 2- BC, the ORR was 70.0%, cORR was 70.0%, DCR was 95.0%, mDoR was 13.7 months, mPFS was 15.2 months, and the 12 and 18-month OS rate was 85.9% and 72.6%, respectively. In 27 patients with TNBC, the ORR was 55.6%, cORR was 55.6%, DCR was 77.8%, mDoR was 5.8 months, mPFS was 7.2 months, and the 12 and 18-month OS rate was 83.9% and 75.5%, respectively.

Safety Data. As of the data cut-off date (July 31, 2025), the observed toxicities were predominantly hematologic. The most common Grade 3 TRAEs were hematologic toxicities, including anemia (50.8%), leukopenia (39.7%), neutropenia (49.2%), and thrombocytopenia (35.2%). Six ILD cases (3%) were reported, including four at Grade 1 to 2, and two at Grade 3. The MTD was 5.6 mg/kg D1 Q3W, and the RP2D for BC was set to be 4.4 mg/kg D1 Q3W.

Phase II Clinical Trial of T-Bren in Combination with Pertuzumab for Unresectable Locally Advanced or Metastatic HER2+ BC (NCT06445400)

This is a Phase II clinical study designed to evaluate the efficacy, safety and tolerability of T-Bren as monotherapy and in combination with pertuzumab in treatment-naïve patients with unresectable locally advanced or metastatic HER2+ BC. The primary endpoints of this trial are ORR, combination RP2D and combination regimen. The secondary endpoints include PFS, DCR, DoR and TEAEs. The exploratory endpoints include PK, immunogenicity and OS.

Trial Design. Eligible patients in this study must have histologically or cytologically confirmed unresectable locally advanced or metastatic HER2+ BC, defined as IHC 3+ or IHC 2+/ISH+, at least one measurable lesion per RECIST v1.1, and an ECOG performance status of 0 or 1. Eligible patients must be treatment-naïve in the unresectable locally advanced or metastatic setting and must have either no brain metastases or stable brain metastases at screening. The study includes two cohorts. In Cohort A, patients receive T-Bren monotherapy at 4.4 mg/kg on D1 Q3W. In Cohort B, patients receive T-Bren at 4.4 mg/kg on D1 Q3W in combination with pertuzumab, with pertuzumab administered at an initial dose of 840 mg followed by 420 mg on D1 Q3W.

Trial Status. This study was initiated in China in June 2024, and the primary endpoints were reached in July 2025. Based on the data from this Phase II trial, we initiated the Phase III registrational trial of T-Bren in combination with pertuzumab as first-line treatment for HER2+ BC (NCT07518173) in April 2026 and is currently ongoing.

Efficacy Data. As of the data cut-off date (March 1, 2026), all 83 enrolled patients were included in the efficacy analysis, with a median follow-up of 13.1 months. In the overall population, T-Bren as monotherapy or in combination with pertuzumab achieved an ORR of 90.4%, a cORR of 88.0% and a DCR of 98.8%. Median DoR and median PFS had not been reached, and the 12-month PFS rate and 12-month OS rate were 87.8% and 97.5%, respectively. In Cohort A, T-Bren monotherapy achieved an ORR of 93.0%, a cORR of 88.4% and a DCR of 100.0%, with a 12-month PFS rate of 83.8% and a 12-month OS rate of 100.0%. In Cohort B, T-Bren in combination with pertuzumab achieved an ORR and cORR of 87.5%, a DCR of 97.5%, a 12-month PFS rate of 90.8% and a 12-month OS rate of 95.0%.

Safety Data. T-Bren as monotherapy or in combination with pertuzumab demonstrated a manageable safety profile in treatment-naïve patients with HER2-positive unresectable locally advanced or metastatic BC. Grade ≥3 TRAEs were effectively managed through standard supportive care. The TRAE-related treatment discontinuation rate was 4.8%, and the dose reduction rate was 50.6%. No treatment-related death or ILD event was reported.

GC/GEJ

Phase I and II Clinical Trials of T-Bren as Monotherapy for Previously Treated HER2+ Advanced GC or GEJ

These open-label, multicenter Phase I and II studies comprised three studies (NCT05461768, NCT05631964, NCT06031584), which enrolled patients with previously treated HER2+ or HER2-low advanced GC/GEJ cancer. All enrolled patients received T-Bren at doses ranging from 2.6 mg/kg to 7.4 mg/kg Q3W. For studies NCT05461768 and NCT05631964, the primary endpoints were DLT, MTD, and RP2D, and the secondary endpoints included safety, ORR, DCR, DoR, PK, PFS, OS, and immunogenicity. For study NCT06031584, the primary endpoints were RP2D and ORR, while the secondary endpoints included safety, DCR, DoR, PFS, PK profile, and immunogenicity.

Trial Design. These studies enroll patients with inoperable, locally advanced or metastatic HER2+ or HER2-low GC/GEJ cancer and other GI tumors. Eligible patients had ECOG performance status 0–1, at least one measurable lesion per RECIST v1.1, adequate organ and marrow function, and had failed, had no access to, or were not suitable for standard therapy. During dose escalation, patients received T-Bren intravenously at doses ranging from 2.6 to 7.4 mg/kg Q3W. In the dose-expansion phase, patients were treated at 3.8, 4.4, 5.0, and 5.6 mg/kg Q3W.

Trial Status. The three studies were initiated in August 2022 (NCT05461768), January 2023 (NCT05631964) and January 2024 (NCT06031584), respectively. Their primary endpoints are expected to be reached in 2026. Based on the data from these three trials, we initiated a Phase III trial (NCT07152405) evaluating T-Bren monotherapy for HER2+ locally advanced or metastatic GC/GEJ after failure of first-line anti-HER2 therapy in September 2025, which is currently ongoing.

Efficacy Data. As of the data cut-off date (July 31, 2025), 76 response-evaluable patients with previously treated HER2+ or HER2-low advanced GC/GEJ cancer had received T-Bren across multiple dose levels. The overall ORR was 55.3% and cORR was 47.4%, with a mDoR of 7.4 months, mPFS of 8.4 months after a median follow-up of 9.0 months, median follow-up for OS of 10.4 months and mOS not yet been reached. Notably, at the 5.0 mg/kg D1 Q3W dose level, the ORR was 57.6% and cORR was 48.5%. Tumor shrinkage was observed in 89.4% (59/66) of patients, with a median (range) reduction of -44.5% (-100.0 to -1.0).

Safety Data. As of the data cut-off date (July 31, 2025), TRAEs were observed in 98.7% of patients, with Grade ≥3 TRAEs reported in 86.8%. The most common toxicities were hematologic, including anemia (89.5%), leukopenia (86.8%), thrombocytopenia (80.3%), and neutropenia (78.9%). The median time to resolution of Grade 3 or 4 neutropenia was 5–6 days, and most patients experienced only one episode. Two Grade 2 treatment-related ILD, including one at 5.0 mg/kg D1Q3W and one at 6.2 mg/kg D1Q3W, were reported.

Clinical Development Plan

T-Bren is our second Core Product and a key demonstration of the repeatable productivity of our HIRE-ADC platform beyond iza-bren. Based on its encouraging clinical activity in HER2-expressing BC, UC and GC/GEJ, and its advancement into multiple pivotal Phase III registrational trials, our development strategy for T-Bren is to establish a broad HER2-targeted pan-tumor franchise. We are advancing T-Bren in later-line monotherapy settings, in combination regimens, and in earlier lines of therapy — including first-line, neoadjuvant, and adjuvant settings — with the aim of capturing large-market HER2-expressing indications while demonstrating the scalability of our ADC discovery and development engine.

As of the Latest Practicable Date, we were conducting 18 clinical trials for T-Bren in China and overseas, including eight Phase III and one Phase II/III registrational trials. In monotherapy, we are advancing Phase III trials for HER2+ pan-tumor indications, including BC, GC/GEJ, NSCLC, BTC and OC. In combination settings, we are conducting a Phase III trial of T-Bren with pertuzumab for first-line HER2+ BC.

Material Communications with Competent Authorities

China

Monotherapy. We received IND approval from the NMPA in July 2022 for the initiation of T-Bren's clinical trials for solid tumors as monotherapy. Under the IND approval, we were permitted to conduct clinical evaluation of T-Bren across multiple types of solid tumors as monotherapy, while further advancement into Phase III or potentially registrational trials in China required subsequent formal communications with the CDE. We subsequently initiated Phase I, Phase Ib/II or Phase II trials in China to explore T-Bren's potential across various solid tumors, including BC, GIC, gynecologic cancers, urinary and gastrointestinal tumors, digestive tract tumors and NSCLC, among others.

Combination therapies, adjuvant and neoadjuvant treatments. We submitted and obtained separate IND approvals from the NMPA for multiple combination therapy regimens to support the expansion of T-Bren's clinical development in combination settings. Following the primary completion of the HER2+ BC cohort in our Phase I clinical trial of T-Bren as a monotherapy for BC (NCT05461768), in April 2024, we obtained IND approval for T-Bren in combination with pertuzumab in HER2+ BC. In addition, in the same month, we also obtained IND approvals of T-Bren in combination with PD-1 monoclonal antibody in GC/GEJ and NSCLC. In January and February 2025, we received additional IND approvals from the NMPA to initiate T-Bren's clinical trials for adjuvant and neoadjuvant treatments of HER2+ BC.

Pre-Phase III communications. Based on the encouraging Phase I data, we have completed pre-Phase III communications with the CDE and initiated Phase III registrational trials across over five major indications. All Phase III trials were initiated following the completion of pre-Phase III communications, and the CDE did not raise any major concerns or objections to the proposed trial designs.

- BC. Apart from a Phase III trial for adjuvant treatment of HER2+ BC, we are conducting three Phase III trials for T-Bren in BC in China: two clinical trials assessing T-Bren as a monotherapy and one clinical trial assessing T-Bren as part of a combination therapy. We obtained no objection from the NMPA to the commencement of the two monotherapy Phase III clinical trials based on the results obtained from the Phase I clinical trial (NCT05461768) described above under "Phase I Clinical Trial of T-Bren as Monotherapy for Locally Advanced or Metastatic BC and Other Solid Tumors (NCT05461768)."

    - (1) HER2+ BC (second-line and beyond monotherapy). The primary endpoints for the HER2+ BC cohort in our Phase I trial (NCT05461768) had been reached as of December 2023. Based on the data from this cohort, we submitted a pre-Phase III communication request to the CDE in December 2023. In March 2024, the CDE expressed no major concerns on the preliminary results of HER2+ BC cohort and no objection to our commencement of the Phase III trial. The Phase III trial (NCT06316531) was initiated in May 2024. Patient enrollment has been completed and the trial is in follow-up visit stage.

    - (2) HER2-low BC (second-line and beyond monotherapy). The primary endpoints for the HER2-low BC cohort in our Phase I trial (NCT05461768) had been reached as of November 2024. Based on the data from this cohort, we submitted a pre-Phase III communication request to the CDE in February 2025. In April 2025,

the CDE expressed no major concerns on the preliminary results of HER2-low BC cohort and no objection to our commencement of the Phase III trial. The Phase III trial (NCT06957886) was initiated in May 2025 and is currently ongoing.

- (3) HER2+ BC (first-line combination with pertuzumab). We initiated our Phase II trial in unresectable locally advanced or metastatic HER2+ BC (NCT06445400) in June 2024. The primary endpoints of this trial had been reached as of July 2025, and based on the data from this trial, we submitted a pre-Phase III communication request in November 2025. In December 2025, the CDE expressed no major concerns on the preliminary results of Phase II combination trial and no objection to our commencement of the Phase III trial. The Phase III trial (NCT07518173) was initiated in April 2026 and is currently ongoing.

- GC/GEJ. We enrolled patients with previously treated HER2+ or HER2-low expressing advanced GC/GEJ cancer in three Phase I or Phase Ib/II trials (NCT05461768, NCT05631964, NCT06031584). Based on data as of March 2025, we submitted a pre-Phase III communication request in June 2025. In August 2025, the CDE expressed no major concerns on the preliminary results of these Phase I and Phase Ib/II trials and no objection to our commencement of the Phase III trial. The Phase III trial (NCT07152405) evaluating T-Bren monotherapy for HER2+ locally advanced or metastatic GC/GEJ after failure of first-line anti-HER2 therapy was initiated in September 2025 and is currently ongoing.

- Other indications. We also submitted pre-Phase III communication requests for (1) HER2-mutant NSCLC in June 2025, (2) HER2-expressing platinum-resistant recurrent epithelial OC, fallopian tube cancer and primary peritoneal cancer in January 2026, and (3) HER2-expressing BTC in February 2026. The CDE did not raise any major concerns or objections to the proposed trial designs for any of these registrational programs. These Phase III trials are currently ongoing.

The U.S.

We received IND approval from the FDA in December 2023 for the initiation of T-Bren's clinical trials for HER2-expressing solid tumors as monotherapy in the U.S. We initiated the Phase I trial in February 2024.

We plan to maintain close communications with the NMPA and FDA at key milestones of T-Bren's ongoing clinical development, including pre-NDA communications for our registrational programs as pivotal trial data mature. We did not receive any major concerns or objections from the above-mentioned regulatory authorities with respect to the clinical development plans for T-Bren.

T-BREN MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

BL-M14D1 (DLL3 ADC)

BL-M14D1 is an innovative DLL3-directed ADC designed for the treatment of advanced SCLC, neuroendocrine neoplasms and other solid tumors. DLL3 is overexpressed in up to 80% of SCLC and other neuroendocrine neoplasms, with low expression in normal tissues, making it an attractive therapeutic target for ADC-based approaches. SCLC is an aggressive form of lung cancer that accounts for approximately 15% of all lung cancer cases, with a global incidence of approximately 372.6 thousand cases in 2025 and an expected increase to approximately 560.9 thousand cases by 2035, according to CIC. Neuroendocrine carcinoma ("**NEC**") represents a heterogeneous group of malignancies with a growing incidence and limited effective treatment options beyond first-line therapy, with an estimated 86.4 thousand new cases globally in 2025, according to CIC.

BL-M14D1 is developed on our HIRE-ADC platform, comprising a human anti-DLL3 monoclonal antibody conjugated to our potent topoisomerase I inhibitor Ed-04 via a stable enzyme-cleavable linker. Upon binding to DLL3 on tumor cells, BL-M14D1 is internalized and delivers its cytotoxic payload Ed-04 intracellularly, inducing tumor cell death. The released Ed-04 can also exert bystander killing effects on neighboring tumor cells, and the Fc portion of the antibody can mediate ADCC effects, further enhancing antitumor activity.

In our Phase I trial to evaluate BL-M14D1 as monotherapy in patients with locally advanced or metastatic SCLC, NEC and other solid tumors, BL-M14D1 has demonstrated promising antitumor activity with a tolerable safety profile. As of the data cut-off date (March 1, 2026), among SCLC patients, BL-M14D1 achieved an ORR of 71.4% (cORR of 60.7%), a DCR of 94.0%, and an mPFS of 7.1 months. Among NEC patients, the ORR was 55.9% (cORR 38.2%), DCR was 94.1%, and the 6-month PFS rate was 56.7%. The most common TRAEs were hematologic and clinically manageable, with only 2.4% of patients discontinuing treatment due to TRAEs. These results were presented as an oral presentation at the 2026 ASCO Annual Meeting.

We initiated this Phase I clinical trial in China in August 2024 and expect to complete this trial in 2026. In addition, we are conducting a Phase I clinical trial of BL-M14D1 in the U.S. for locally advanced or metastatic SCLC and neuroendocrine tumors, and expect to complete this trial in 2027. In July 2026, we also initiated a Phase II trial in China evaluating BL-M14D1 in combination with atezolizumab for ES-SCLC, which we expect to complete in 2027. We also initiated a Phase III multi-regional clinical trial evaluating BL-M14D1 in combination with atezolizumab versus standard-of-care therapy in patients with previously untreated ES-SCLC in the same month. Standard-of-care therapy consists of carboplatin plus etoposide chemotherapy and atezolizumab, followed by maintenance treatment with atezolizumab with or without lurbinectedin. We plan to enroll approximately 550 patients with advanced ES-SCLC. This is our first independently initiated global Phase III trial. We expect to complete this global trial in 2030.

BL-M14D1 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

BL-M05D1 (Claudin 18.2 ADC)

BL-M05D1 is an innovative Claudin 18.2-targeted ADC and is currently being evaluated in three clinical trials across China and the U.S. Claudin 18.2 is predominantly expressed in the gastric mucosa and typically absent from other healthy tissues; however, its overexpression has been identified in 30% to 50% of GC, pancreatic cancer and BTC cases, making it an attractive therapeutic target. GC is one of the most prevalent and lethal cancers globally, with an estimated 1,036.8 thousand new cases and approximately 660 thousand deaths worldwide in 2025, according to CIC. In China, GC incidence reached approximately 335.5 thousand cases in 2025 representing a substantial addressable patient population with unmet medical needs, particularly in the second-line and beyond setting where effective treatment options remain limited.

BL-M05D1 comprises an in-house developed Claudin 18.2 monoclonal antibody conjugated to our potent topoisomerase I inhibitor, Ed-04, via a cathepsin B cleavable linker with a DAR of 8. Upon binding to Claudin 18.2, BL-M05D1 is internalized and trafficked to lysosomes, where the linker is cleaved to release Ed-04, inducing tumor cell death. The Fc portion of the antibody can also mediate ADCC/complement-dependent cytotoxicity ("**CDC**") effects, further enhancing antitumor activity. BL-M05D1 is designed with a high degree of specificity for Claudin 18.2, and our proprietary linker ensures stability in the bloodstream and controlled payload release upon internalization, maximizing therapeutic efficacy while minimizing systemic toxicity.

In our Phase I clinical trial, BL-M05D1 has demonstrated promising antitumor activity with a tolerable safety profile across multiple Claudin 18.2-expressing tumor types. As of the data cut-off date (March 30, 2026), BL-M05D1 achieved an ORR of 41.5% (cORR of 37.7%), an mPFS of 5.5 months and an mOS of 12.8 months in GC/GEJ; an ORR of 26.3% (cORR of 23.7%), an mPFS of

4.4 months and an mOS of 14.2 months in pancreatic cancer; and an ORR of 42.5% (cORR of 32.5%), an mPFS of 5.7 months and mOS not reached in BTC. The most common TRAEs were hematologic and clinically manageable, with no new safety signals observed. These results were presented at the 2026 ASCO Annual Meeting.

We are currently conducting three clinical trials for BL-M05D1 in China and the U.S. In addition to the Phase I trial in China, we initiated a Phase I clinical trial in the U.S. in July 2025 for Claudin 18.2-expressing locally advanced or metastatic solid tumors, which is currently in the Phase Ia stage. Based on the Phase I data in GC/GEJ cohort, we initiated a Phase III registrational trial in May 2026 in China to evaluate BL-M05D1 as monotherapy for Claudin 18.2+ advanced GC/GEJ. We expect this Phase III trial to be completed in 2029.

BL-M05D1 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

BL-M11D1 (CD33 ADC)

BL-M11D1 is an innovative CD33 specific ADC. BL-M11D1 is currently being evaluated in four clinical trials in the U.S. and China for hematologic malignancies, including relapsed/refractory acute myeloid leukemia ("**AML**") and myelodysplastic syndromes.

CD33 is a transmembrane receptor expressed on cells of myeloid lineage and is broadly overexpressed in hematologic malignancies. Approximately 85% to 90% of AML patients express CD33 on their leukemia cells, supporting CD33 as a promising selective therapeutic target in AML. AML is the most common acute leukemia in adults, with an estimated 155 thousand new cases globally and 19 thousand new cases in China in 2025, according to CIC. Despite advances in treatment, the prognosis for relapsed or refractory AML patients remains poor, with limited effective therapies available and a five-year survival rate of approximately 33%, representing a significant medical need.

BL-M11D1 consists of gemtuzumab, a CD33-targeting monoclonal antibody with a wild-type Fc region that can mediate ADCC, conjugated to our novel Topo1 inhibitor, Ed-04, via a cathepsin B-cleavable linker with a DAR of 10. Upon binding to CD33 on tumor cells, BL-M11D1 is internalized through endocytosis and releases Ed-04 in lysosomes through enzymatic cleavage. Ed-04 blocks DNA synthesis and induces tumor cell death, while the Fc region of BL-M11D1 further enhances tumor cell killing through ADCC. Our preclinical studies showed that BL-M11D1 may offer better tolerability and a wider therapeutic window, compared with gemtuzumab ozogamicin, a marketed CD33 ADC.

In our Phase I monotherapy trial in China, BL-M11D1 demonstrated encouraging anti-leukemic activity in patients with relapsed/refractory AML. As of the efficacy data cut-off date (July 25, 2024), the ORR, including complete remission, complete remission with incomplete count recovery ("**CRi**") and morphologic leukemia-free state ("**MLFS**"), was 14.3%, 40.0% and 50.0% at the 1.65 mg/kg, 2.2 mg/kg and 2.75 mg/kg dose levels, respectively. One complete remission was sustained for over six months. As of the safety data cut-off date (September 30, 2024), BL-M11D1 exhibited an acceptable safety profile. No Grade 3 or higher organ injury or veno-occlusive disease ("**VOD**") was observed. Together with its overall manageable safety profile, the absence of observed VOD to date may support the future clinical evaluation of BL-M11D1 in broader AML treatment settings. The Phase I trial was initiated in August 2023, and is expected to be completed in 2026.

In addition, we have initiated a Phase I clinical study for BL-M11D1 for the treatment of patients with relapsed/refractory AML in the U.S., and we expect to complete this trial in 2026. Beyond as monotherapy, we are also exploring the combination potential of BL-M11D1 with cytarabine and daunorubicin or venetoclax and azacitidine for the treatment of AML in China. We

initiated a Phase II/III trial in March 2026 and expect to complete the trial in 2027. We are also conducting a Phase Ib/II trial of BL-M11D1 as monotherapy for relapsed/refractory myelodysplastic syndromes in China, which was initiated in May 2026 and is expected to be completed in 2028.

BL-M11D1 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

Other HIRE-ADC Candidates

We are also advancing other HIRE-ADC candidates, including:

BL-B16D1. BL-B16D1 is an innovative bispecific ADC with a proprietary new-generation payload developed on our platform. We are currently conducting three Phase I clinical trials for BL-B16D1 in China. The first trial, for the treatment of HNSCC and other solid tumors, initiated patient enrollment in June 2024. The other two trials, including one for the treatment of solid tumors and one for BC and solid tumors, were initiated in July and August 2024, respectively. The Phase Ia stages of all three trials have been completed and the Phase Ib stages are ongoing. All three clinical trials are expected to be completed in 2026.

BL-M08D1. BL-M08D1 is an innovative ADC developed on the same proprietary small-molecule technology platform as iza-bren, sharing the identical linker-toxin architecture. As of the Latest Practicable Date, BL-M08D1 was undergoing two Phase I clinical trials in China, targeting relapsed or refractory lymphoid malignancies and locally advanced or metastatic solid tumors, respectively. The Phase Ia stages of both trials have been completed and the trials are expected to be completed in 2027 and 2026, respectively.

BL-M09D1. BL-M09D1 is an innovative ADC developed from the same proprietary small molecule technology platform as iza-bren, sharing the same linker-toxin technology. As of the Latest Practicable Date, we were conducting two Phase I clinical trials of BL-M09D1 for the treatment of locally advanced or metastatic gastrointestinal malignancies, NSCLC and other solid tumors in China. The Phase Ia stages of both trials have been completed, and both trials are expected to be completed in 2027.

BL-M24D1. BL-M24D1 is an innovative ADC for the treatment of solid tumors. As of the Latest Practicable Date, we were conducting four Phase I clinical trials of BL-M24D1 as monotherapy in China, covering locally advanced or metastatic NSCLC, GIC, HNSCC and other solid tumors, as well as recurrent or refractory multiple myeloma and other hematologic malignancies. The Phase Ia stages of all these trials are ongoing, and the trials are expected to be completed in 2027.

BL-B16D1, BL-M08D1, BL-M09D1 AND BL-M24D1 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

Biologics Portfolio Empowered by GNC Platform

GNC (Guidance Navigation & Control) is our proprietary, self-developed platform focused on multi-specific antibody development. It is designed to develop multi-specific antibodies with symmetrical/asymmetrical structures that can simultaneously target multiple different antigens. Multi-specific GNC molecules developed on this platform coordinate interactions among several immune-related protein domains to synergistically and comprehensively modulate the immune system. These GNC compounds guide, navigate, and control the immune cells, ultimately leading to a targeted elimination of pathogenic cells and the restoration of immune homeostasis. We are committed to advancing clinical trials for our first-generation GNC drug candidate, GNC-038 (CD3 × 4-1BB × PD-L1 × CD19), focusing on severe autoimmune diseases.

GNC-038 (CD3 × 4-1BB × PD-L1 × CD19)

GNC-038 is an innovative, recombinant humanized tetra-specific antibody that targets CD3, 4-1BB, PD-L1 and CD19. According to CIC, GNC-038 is the first tetra-specific therapeutic antibody to enter clinical development and be tested in human globally.

CD3 is a T cell co-receptor essential for T cell activation and function. CD3-targeted therapies aim to redirect T cells to tumor cells, enabling the immune system to recognize and eliminate them. 4-1BB (CD137) is a costimulatory receptor on T cells that enhances T cell proliferation and survival, thereby strengthening the targeted immune responses. PD-L1 is an immune checkpoint protein and modulating the PD-1/PD-L1 pathway can help regulate immune overactivation and reshape the inflammatory microenvironment. CD19 is broadly expressed on B cells from early development through maturity including the autoreactive B cells responsible for producing auto-antibodies in autoimmune diseases, making it an attractive therapeutic target for redirected T-cell cytotoxicity.

This multi-target design enables GNC-038 to coordinate T-cell redirection, costimulatory activation, immune checkpoint modulation to effectively deplete pathogenic B cells within a single molecule. By deeply clearing these autoreactive B cells, GNC-038 has the potential to achieve an "immune reset" and provide more potent and sustained therapeutic responses for autoimmune diseases than conventional therapies. In our preclinical studies, GNC-038 effectively drives T cell-mediated killing of target B cells and modulates cytokine release, suggesting its potential to safely and effectively restore immune balance in patients with severe autoimmune conditions.

We are advancing two Phase I clinical trials for GNC-038 in China in autoimmune indications, rheumatoid arthritis and systemic lupus erythematosus. These trials are expected to be completed in 2027.

GNC-038 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

Biologics Portfolio Empowered by SEBA Platform

Our "Specificity Enhanced Bispecific Antibody," or SEBA, platform is our proprietary, self-developed bispecific antibody platform. SEBA molecules are able to not only block growth signals that cancer cells rely on for survival, but also induce greater immune system activity for greater potency and selectivity while minimizing off-target effects. Products developed from our SEBA platform include SI-B001 (EGFR × HER3 bispecific antibody), SI-B003 (PD-1 × CTLA-4 bispecific antibody) and SI-B036.

SI-B001 (EGFR × HER3 bispecific antibody)

SI-B001, also known as izalontamab, is a potentially first-in-class EGFR × HER3 bispecific antibody. According to CIC, SI-B001 is currently the only clinical-stage bispecific antibody in the world that simultaneously targets EGFR and HER3.

SI-B001 is a tetravalent bispecific antibody comprising two binding domains for each of EGFR and HER3. It is designed with a spatial configuration that enables HER3 binding only after successful engagement of EGFR. This conditional binding minimizes HER3 binding in normal tissues and promotes selective accumulation in tumor cells co-expressing EGFR and HER3, thereby enhancing tumor inhibition while reducing effects on normal tissues compared with a combination of two monoclonal antibodies. Mechanistically, SI-B001 simultaneously inhibits signaling from EGFR × EGFR homodimers and EGFR × HER3 heterodimers and their downstream pathways, induces internalization and degradation of EGFR and HER3 on tumor cells, and can mediate ADCC effects through its wild-type Fc region. For details on the biological roles of EGFR and HER3, see "— HIRE-ADC Platform — iza-bren (EGFR × HER3 bispecific ADC) — Mechanism of Action."

Clinical studies have demonstrated SI-B001's encouraging antitumor activity and manageable safety in HNSCC. In a Phase II trial evaluating SI-B001 in combination with paclitaxel in patients with recurrent or metastatic HNSCC who had progressed on prior PD-(L)1 therapy, SI-B001 plus paclitaxel achieved an ORR of 58.2%, a DCR of 82.4%, an mDoR of 3.9 months and an mPFS of 5.4 months as of the same data cut-off date. In addition, updated HNSCC data from an expanded cohort were presented at the 2026 ASCO Annual Meeting, showing an ORR of 52.9% (confirmed ORR 41.2%), a DCR of 73.5%, an mPFS of 5.4 months and an mOS of 11.2 months. In patients with only one prior line of therapy, the ORR was 53.8% (confirmed ORR 46.2%) and mOS was 17.9 months.

We are advancing four clinical trials for SI-B001 in China in HNSCC and NSCLC in combination settings, including in combination with chemotherapy and SI-B003. All these trials were in follow-up visit stage as of the Latest Practicable Date.

SI-B001 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SI-B003 (PD-1 × CTLA-4 bispecific antibody)

SI-B003 is a bispecific antibody targeting both PD-1 and CTLA-4, designed to restore antitumor immune function by simultaneously blocking two key immune checkpoint pathways. PD-1 signaling on T cells leads to immune suppression and enables cancer cells to evade immune detection, while CTLA-4 is crucial for regulatory T cell ("**Treg**") function and inhibits antitumor immunity. By binding to both PD-1 and CTLA-4 on tumor-infiltrating lymphocytes, SI-B003 inhibits the checkpoint-mediated downregulation of T cell activation and proliferation, restoring a sustained cytotoxic T-lymphocyte-mediated immune response against tumor cells. As a dual checkpoint inhibitor, SI-B003 has demonstrated promising efficacy that outperforms individual PD-1 or CTLA-4 inhibitors, and as monotherapy has shown encouraging efficacy and favorable safety profiles in patients with various solid tumors. Notably, SI-B003's Fc region has been redesigned to minimize toxicity by reducing the potential for ADCC. SI-B003 is also positioned as a key component in combination therapies alongside SI-B001 and iza-bren, where the combination is expected to achieve synergistic antitumor effects.

We are currently conducting one Phase I clinical trial for SI-B003 as monotherapy for advanced solid tumors in China. The Phase I trial was initiated in November 2020. As of the Latest Practicable Date, the database lock had been completed. We are exploring the combination therapy of SI-B003 with our other pipeline drug candidates. For details, see "— HIRE-ADC Platform — iza-bren (EGFR × HER3 bispecific ADC) — Summary of Clinical Trial Data" and "— SEBA Platform — SI-B001 (EGFR × HER3 bispecific antibody)."

SI-B003 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

Other SEBA Candidates

We are also advancing other bispecific antibody candidates, including SI-B036. We initiated a Phase I clinical trial evaluating SI-B036 in locally advanced or metastatic solid tumors as monotherapy in June 2026. This trial is expected to be completed in 2028.

SI-B036 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

Biologics Portfolio Empowered by HIRE-ARC Platform

Leveraging our expertise in antibody and ADC technologies, we have established a proprietary platform for the development of ARCs, the HIRE-ARC platform, which integrates the precise antibody-mediated targeted delivery with the potent tumor-killing capabilities of radionuclides. Compared to traditional RDCs, ARC therapies offer enhanced target specificity, improved tumor accumulation, and greater ability to overcome drug resistance.

BL-ARC001 is our first innovative ARC drug candidate developed on the HIRE-ARC platform, with full proprietary intellectual property rights. BL-ARC001 is a potentially first-in-class ARC labeled with the radioisotope ^{177}Lu, designed for the treatment of relapsed or refractory malignant solid tumors. We obtained the IND approval from the NMPA for BL-ARC001 in September 2025, and are currently conducting two Phase I clinical trials in China: one for locally advanced or metastatic gastrointestinal tumors and other solid tumors which was initiated in November 2025, and one for locally advanced or metastatic solid tumors which was initiated in December 2025. Both trials are currently in the Phase Ia stage.

BL-ARC002 is our next-generation ARC drug candidate, featuring a novel linker-radionuclide integration unit platform, designed for the treatment of relapsed or refractory malignant tumors. We obtained the IND approval from the NMPA for BL-ARC002 in March 2026, and initiated a Phase I clinical trial in China for locally advanced or metastatic solid tumors in May 2026. This trial is currently in the Phase Ia stage.

BL-ARC001 AND BL-ARC002 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

Our Generics and Traditional Chinese Medicine Products

During the Track Record Period, we generated a portion of our revenue from the sales of 31 approved generics (covering a wide range of therapeutic areas such as anesthesia, parenteral nutrition, pediatric and anti-infective drugs) and traditional Chinese medicine products with over 100 specifications. As of the Latest Practicable Date, we had submitted four generic drug applications for production registration with the NMPA and expect additional products to be approved for commercialization in the future. Revenue from our marketed generics and traditional Chinese medicine products has played a crucial role in financially supporting our innovative drug development. Moving forward, the R&D and commercialization of our innovative drugs will serve as our core strategic focus and primary growth driver.

The following table summarizes our major generics and traditional Chinese medicine products, which contributed over 5% of our total revenue from the sales of pharmaceutical products in any of 2024, 2025 or the three months ended March 31, 2026:

Therapeutic Area	Product	Sample Picture	Type	Indication	Inclusion in NRDL[1]	Participation in VBP	Retail Price Range[3] (RMB)
Generic Drugs							
Anesthesia Drugs	Leweijing 乐维静® (Propofol Injectable Emulsion (丙泊酚乳状注射液))		Prescription only	Short-acting intravenous general anaesthetic for the induction and maintenance of general anaesthesia in adult and pediatric patients over the age of one month	Yes, Part A	Yes[2]	1.8-48.7
	Leweitai 乐维泰® (Propofol Medium and Long Chain Fat Emulsion Injection (丙泊酚中/長鏈脂肪乳注射液))		Prescription only	Short-acting general anesthetic for the induction and maintenance of general anesthesia in adult and pediatric patients over the age of one month, and for sedation in patients over 16 years of age undergoing mechanical ventilation in intensive care	Yes, Part B	Yes[2]	4.5-193.8
	Shuweijing 舒维静® (Sevoflurane for Inhalation (吸入用七氟烷))		Prescription only	Inhalational anesthetic indicated for the induction and maintenance of general anesthesia in adult and pediatric patients, including both inpatient and outpatient settings	Yes, Part B	Yes[2]	263.8-1,305.0
Parenteral Nutrition Drugs	Tianze 天泽® (Medium and Long Chain Fat Emulsion Injection (中/長鏈脂肪乳注射液))		Prescription only	For the supplementation of energy and essential fatty acids when oral or enteral nutrition is not possible or sufficient	Yes, Part B	Yes[2]	13.0-79.7
	Bailineng 百利能® (Structural Fat Emulsion Injection (C6-24) (結構脂肪乳注射液))		Prescription only	As a component of parenteral nutrition to provide energy and essential fatty acids	Yes, Part B	Yes[2]	193.7-195.7

Therapeutic Area	Product	Sample Picture	Type	Indication	Inclusion in NRDL[(1)]	Participation in VBP	Retail Price Range[(3)] (RMB)
Pediatric Drugs	Leyeping 乐液平® and Pujikang 朴吉康® (Glucose Electrolyte Effervescent Tablet (葡萄糖電解質泡騰片))	 	Prescription only	Prevention and treatment of mild to moderate dehydration due to diarrhea and vomiting, as well as due to prolonged and strenuous physical activity	No	No	44.9-540.0
Traditional Chinese Medicine							
	Astragalus Granule (黃芪顆粒)		Prescription/ over-the-counter ("**OTC**")	Prescription: Qi-deficiency, diuretic, toxin-drainage and pus discharge, and muscle growth. Used in treating shortness of breath, palpitation, defecation, spontaneous sweating, swelling, prolonged diarrhea, prolapse of anus, prolapse of uterus, carbuncle and gangrene, sores that do not heal for an extended period of time OTC: Qi-deficiency. For shortness of breath, palpitation, spontaneous sweating	Yes, Part B	No	20.2-498.0

Notes: (1) The NRDL comprises Part A and Part B. Patients purchasing pharmaceuticals included in Part A of the NRDL are entitled to reimbursement of the entire amount of the purchase price, while patients purchasing pharmaceuticals included in Part B of the NRDL are required to pay a deductible amount and obtain reimbursement for the remainder of the purchase price. The amount of the deductible differs from region to region in the PRC. In principle, the NRDL was subject to a dynamic adjustment entitled to once a year. (2) See "— Generic Drugs" for details of the relevant products' participation in the VBP schemes. (3) Retail price range represents the lowest retail price and highest retail price of the relevant product during the Track Record Period, covering respective specifications.

The following table sets forth our revenue contribution from the sales of our major generics and traditional Chinese medicine products for the periods indicated:

	Year ended December 31,				Three months ended March 31,			
	2024		2025		2025		2026	
	Amount	%	Amount	%	Amount	%	Amount	%
	(RMB in thousands, except for percentages)				*(Unaudited)*			
Major anesthesia drugs								
Leweijing	131,869	27.1	83,487	22.0	10,484	17.3	21,384	23.2
Leweitai	26,337	5.4	21,858	5.8	3,792	6.3	5,721	6.2
Shuweijing	46,009	9.5	40,956	10.8	6,142	10.2	13,013	14.1
Major parenteral nutrition drugs								
Tianze	27,245	5.6	19,610	5.2	4,192	6.9	3,751	4.1
Bailineng	968	0.2	21,131	5.6	2,954	4.9	8,344	9.1
Major pediatric drugs								
Leyeping and Pujikang	20,158	4.1	22,959	6.0	5,526	9.1	6,110	6.6
Other chemical drugs								
Anti-infectives	21,473	4.4	17,890	4.7	2,636	4.4	2,977	3.2
Others	48,219	9.9	56,185	14.8	9,482	15.6	12,937	14.0
Traditional Chinese medicine								
Astragalus granule	146,312	30.1	84,077	22.1	13,641	22.5	15,838	17.2
Other traditional Chinese medicines	18,169	3.7	11,922	3.0	1,656	2.8	1,906	2.3
Total	**486,759**	**100.0**	**380,075**	**100.0**	**60,505**	**100.0**	**91,981**	**100.0**

The following table sets forth the sales volume and average selling price of our major generics and traditional Chinese medicine products for the periods indicated:

	Year ended December 31,				Three months ended March 31,			
	2024		2025		2025		2026	
	Sales volume	Average selling price	Sales volume	Average selling price	Sales volume	Average selling price	Sales volume	Average selling price
	('000 units)	*(RMB/ unit)*	*('000 units)*	*(RMB/ unit)*	*('000 units)*	*(RMB/ unit)*	*('000 units)*	*(RMB/ unit)*
Leweijing	15,292	8.6	10,710	7.8	1,380	7.6	2,722	7.9
Leweitai	2,725	9.7	2,556	8.6	453	8.4	692	8.3
Shuweijing	116	396.6	101	405.5	13	472.5	33	394.3
Tianze	990	27.5	717	27.4	144	29.1	139	27.0
Bailineng	6	161.3	140	150.9	19	155.5	57	146.4
Leyeping and Pujikang	654	30.8	931	24.7	197	28.1	210	29.1
Astragalus granule	5,329	27.5	3,149	26.7	518	26.3	587	27.0

Note: Average selling price is calculated by dividing revenue by sales volume.

During the Track Record Period, the sales volume and average selling price of our major generics and traditional Chinese medicine products were affected by various regulatory regimes including the centralized tender process and the VBP, both governing the purchase of drugs by public hospitals and public medical institutions. See "— Pricing — Centralized Tender Process and Volume-based Procurement" for more details.

Generic Drugs

Anesthesia Drugs

As of the Latest Practicable Date, our major anesthesia-related product portfolio consisted of three approved products: (i) propofol injectable emulsion, (ii) propofol medium and long chain fat emulsion injection, and (iii) sevoflurane for inhalation. For details of the competitive landscape of our major anesthesia-related products, see "Industry Overview — Generics and Traditional Chinese Medicines — Generic Medicines — Anesthesia."

Leweijing 乐维静® (propofol injectable emulsion)

Our propofol injectable emulsion, under the brand name Leweijing (乐维静®), was first approved by the NMPA in September 2001. Multiple authoritative guidelines have recommended propofol hydrochloride injection for sedation therapy, highlighting its potential for widespread clinical adoption and sustained market growth. We provide Leweijing in three specifications, including 10ml:0.1g, 20ml:0.2g, and 50ml:0.5g. In 2024, 2025 and the three months ended March 31, 2025 and 2026, our revenue from sales of Leweijing amounted to RMB131.9 million, RMB83.5 million, RMB10.5 million and RMB21.4 million, respectively, representing 27.1%, 22.0%, 17.3% and 23.2% of our total revenue from the sale of pharmaceutical products for the respective periods. Our propofol injectable emulsion has been covered under the National Reimbursement Drug List of China ("**NRDL**") since 2004. It has also been included in the 2018 National Essential Drug List of China ("**NEDL**"). Leweijing was also included in the ninth batch of the national VBP scheme. The scheme was implemented from March 2024 and runs until December 2027, superseding the earlier provincial and provincial-alliance VBP schemes in which Leweijing had participated. As of March 31, 2026, Leweijing was sold in 31 provinces across China primarily through in-hospital channel.

Leweitai 乐维泰® (propofol medium and long chain fat emulsion injection)

Our propofol medium and long chain fat emulsion injection, under the brand name Leweitai (乐维泰®), was first approved by the NMPA in July 2014. We provide Leweitai in four specifications, including 10ml:0.1g, 20ml:0.2g, 50ml:0.5g, and 100ml:1.0g. In 2024, 2025 and the three months ended March 31, 2025 and 2026, our revenue from sales of Leweitai amounted to RMB26.3 million, RMB21.9 million, RMB3.8 million and RMB5.7 million, respectively, representing 5.4%, 5.8%, 6.3% and 6.2% of our total revenue from the sale of pharmaceutical products for the respective periods. Our propofol medium and long chain fat emulsion injection has, since its approval for marketing, been covered under the NRDL by reference to its generic names. Leweitai was included in the national follow-on VBP scheme, which was implemented in March 2026 and has a procurement cycle running until December 31, 2028. This national follow-on VBP scheme superseded the previous VBP schemes in which Leweitai had participated. As of March 31, 2026, Leweitai was sold in 31 provinces across China primarily through in-hospital channel.

Shuweijing 舒维静® (sevoflurane for inhalation)

Our sevoflurane for inhalation, under the brand name of Shuweijing 舒维静®, was first approved by the NMPA in May 2023. We provide sevoflurane in two specifications, including 120 mL and 250 mL bottles compatible with standard vaporizers. In 2024, 2025 and the three months ended March 31, 2025 and 2026, our revenue from sales of Shuweijing amounted to RMB46.0 million, RMB41.0 million, RMB6.1 million and RMB13.0 million, respectively, representing 9.5%, 10.8%, 10.2% and 14.1% of our total revenue from the sale of pharmaceutical products for the respective periods. Our sevoflurane for inhalation has, since its approval for marketing, been covered under the NRDL by reference to its generic names. As of the Latest Practicable Date, Shuweijing was included in selected provincial and provincial-alliance VBP schemes covering more than 10 provincial-level regions, with the latest cycle running until August 2027. Shuweijing is

currently participating in the twelfth batch of the national VBP scheme in 2026, the results of which had not yet been announced as of the Latest Practicable Date. As of March 31, 2026, our sevoflurane for inhalation was sold in 29 provinces across China primarily through in-hospital channel.

Parenteral Nutrition Drugs

As of the Latest Practicable Date, our parenteral nutrition drug portfolio mainly comprised two products, medium and long chain fat emulsion injection and structural fat emulsion injection. For details of the competitive landscape of our major parenteral nutrition drugs, see "Industry Overview — Generics and Traditional Chinese Medicines — Generic Medicines — Parenteral Nutrition."

Tianze 天泽® (medium and long chain fat emulsion injection)

Our medium and long chain fat emulsion injection, under the brand name Tianze (天泽®), was first approved by the NMPA in August 2012. The medium and long chain fat emulsion injection has been highlighted as an ideal parenteral nutrition drug for preventing oxidative stress, which downregulates inflammatory responses and maintains organ function. We provide Tianze (天泽®) in four specifications, including 100ml:20%, 250ml:10%, 250ml:20%, and 500ml:10%. In 2024, 2025 and the three months ended March 31, 2025 and 2026, our revenue from sales of Tianze amounted to RMB27.2 million, RMB19.6 million, RMB4.2 million and RMB3.8 million, respectively, representing 5.6%, 5.2%, 6.9% and 4.1% of our total revenue from the sale of pharmaceutical products for the respective periods. Our medium and long chain fat emulsion injection has, since its approval for marketing, been covered under the NRDL by reference to its generic names. It has also been included in the 2018 NEDL. Tianze was included in the national follow-on VBP scheme, which was implemented in March 2026 and has a procurement cycle running until December 31, 2028. This national follow-on VBP scheme superseded the previous VBP schemes in which Tianze had participated. As of March 31, 2026, Tianze was sold in 27 provinces across China primarily through in-hospital channel.

Bailineng 百利能® (structural fat emulsion injection (C6-24))

Our structural fat emulsion injection (C6-24), under the brand name Bailineng (百利能®) was first approved by the NMPA in June 2024. It is indicated as a component of parenteral nutrition to provide energy and essential fatty acids. We provide Bailineng in one specification, namely, 250ml: 20%. In 2024, 2025 and the three months ended March 31, 2025 and 2026, our revenue from sales of Bailineng amounted to RMB1.0 million, RMB21.1 million, RMB3.0 million and RMB8.3 million, respectively, representing 0.2%, 5.6%, 4.9% and 9.1% of our total revenue from the sale of pharmaceutical products for the respective periods. Our structural fat emulsion injection (C6-24) has, since its approval for marketing, been covered under the NRDL by reference to its generic names. Bailineng was not included in any national VBP scheme. It was included in selected provincial and provincial-alliance VBP schemes across more than 20 provincial-level regions, with procurement cycles ending between December 2026 and March 2028. As of March 31, 2026, Bailineng was sold in 26 provinces across China, primarily through in-hospital channels.

Pediatric Drugs

As of the Latest Practicable Date, our pediatric drug portfolio mainly comprised one product, namely glucose electrolyte effervescent tablet. For details of the competitive landscape of our pediatric drugs, see "Industry Overview — Generics and Traditional Chinese Medicines — Generic Medicines — Pediatric Drugs."

Leyeping 乐液平® and Pujikang 朴吉康® (glucose electrolyte effervescent tablet)

Glucose electrolyte effervescent tablet is oral rehydration product used to replenish fluids and electrolytes and support the management of dehydration associated with diarrhea and other causes. Our glucose electrolyte effervescent tablet, under the brand name Leyeping (乐液平®) and Pujikang

(朴吉康®), was first approved by the NMPA in June 2013. In 2024, 2025 and the three months ended March 31, 2025 and 2026, our revenue from sales of Leyeping and Pujikang amounted to RMB20.2 million, RMB23.0 million, RMB5.5 million and RMB6.1 million, respectively, representing 4.1%, 6.0%, 9.1% and 6.6% of our total revenue from the sale of pharmaceutical products for the respective periods. Glucose electrolyte effervescent tablet was not included in any national or provincial VBP scheme. As of March 31, 2026, Leyeping and Pujikang were sold in 27 provinces across China through both in-hospital and outside-of-hospital channels.

Traditional Chinese Medicine

As of the Latest Practicable Date, our traditional Chinese medicine product portfolio mainly comprised one product, namely astragalus granule. For details of the competitive landscape of astragalus granule, see "Industry Overview — Generics and Traditional Chinese Medicines — Traditional Chinese Medicines."

Astragalus granule

Astragalus granule is an essential product for improving overall health and resilience against chronic ailments. Our astragalus granule was first approved by the NMPA in October 2002. This dominant market presence underscores the efficacy and widespread acceptance of our astragalus granule in clinical practice. In 2024, 2025 and the three months ended March 31, 2025 and 2026, our revenue from sales of Astragalus granule amounted to RMB146.3 million, RMB84.1 million, RMB13.6 million and RMB15.8 million, respectively, representing 30.1%, 22.1%, 22.5% and 17.2% of our total revenue from the sale of pharmaceutical products for the respective periods. Our astragalus granule has been covered under the NRDL since 2004. It was not included in any national or provincial VBP scheme. As of March 31, 2026, our astragalus granules was sold in 30 provinces across China through both in-hospital and outside-of-hospital channels.

LICENSE AND COLLABORATION AGREEMENT WITH BRISTOL-MYERS SQUIBB COMPANY

Overview

On December 11, 2023, we entered into an exclusive license and collaboration agreement with Bristol-Myers Squibb Company ("**BMS**"), effective as of February 8, 2024 (the "**BMS Agreement**"), under which we and BMS will conduct a global strategic license of and collaboration on iza-bren, a bispecific ADC which targets both EGFR and HER3 (the "**Licensed Product**"). Under the BMS Agreement, BMS agreed to pay to us a US$800 million upfront payment and up to US$500 million in contingent near-term payments. In addition, we are eligible to receive additional payments of up to US$7.1 billion contingent upon the achievement of certain development, regulatory and sales performance milestones for a total potential consideration of up to US$8.4 billion. Under the agreement, four joint committees have been established to govern and coordinate the collaboration. BMS and SystImmune will develop iza-bren in the United States in accordance with the global development plan and budget overseen by the joint steering committee and joint development committee. Commercialization of iza-bren in the United States will be conducted pursuant to a commercialization plan and budget jointly developed and finalized by BMS and SystImmune through the joint steering committee and joint commercialization committee. The parties will share certain global development expenses and profits and losses in the U.S., and we retained exclusive rights to develop and commercialize the Licensed Product in Chinese Mainland where BMS will receive a royalty on net sales, and we granted BMS an exclusive license to develop and commercialize the Licensed Product in the rest of the world ("**ROW**") where we will receive a tiered royalty on net sales, subject to certain specified conditions and limitations. As of the signing of the BMS Agreement, we had conducted multiple Phase I/II clinical trials of the Licensed Product in Chinese Mainland, targeting a wide range of solid tumors including, among others, NSCLC, SCLC, BC, HNSCC, NPC and EC, and SystImmune had initiated a Phase I study of the Licensed Product in the U.S. The U.S. Phase I study is currently investigating NSCLC, SCLC, BC, EC and NPC.

Background of the Transaction

BMS, an Independent Third Party, is a leading global biopharmaceutical company focused on discovering, developing and delivering transformational medicines for patients facing serious diseases, including in the area of oncology, among other areas. BMS is renowned for its robust clinical development capabilities, extensive sales and distribution network and a comprehensive oncology portfolio. After reviewing our publicly available clinical data, BMS initiated discussions about a potential collaboration on the Licensed Product. Recognizing the complexity and significant costs associated with developing a pan-tumor treatment such as the Licensed Product, we entered into the BMS Agreement on December 11, 2023. We believe this collaboration allows us to combine resources to expedite development and commercialization while effectively managing the associated costs and risks.

Development and Commercialization by Geographical Regions

In Chinese Mainland, we will have the exclusive right to develop and commercialize the Licensed Product at our cost and will have the final decision-making authority with respect to the conduct of such development and commercialization activities, subject to certain specified conditions and limitations. In the ROW, BMS will have the exclusive right to develop and commercialize the Licensed Product at its cost and will have the final decision-making authority with respect to the conduct of such development and commercialization activities, subject to certain specified conditions and limitations.

In the U.S., pursuant to the BMS Agreement, we and BMS have established a joint steering committee as a forum to oversee and coordinate the parties' activities with regard to the development, manufacture and commercialization of the Licensed Product in the U.S. The joint steering committee will also coordinate and resolve specified issues relating to each party's activities related to the development, manufacture and commercialization of the Licensed Product in each party's respective territories that may adversely affect the development, manufacture and commercialization of the Licensed Product in the U.S.

In addition to the joint steering committee, we and BMS have also established (a) a joint development committee, which will oversee and coordinate the development of the Licensed Product in the U.S. and to resolve disputes regarding safety concerns with respect to the development of the Licensed Products in Chinese Mainland and ROW, (b) a joint finance committee, which will facilitate and coordinate the reporting of financial information under the BMS Agreement and (c) a joint commercialization committee, which will oversee and coordinate the commercialization of the Licensed Product in the U.S. and review and coordinate pricing, discounting and reimbursement matters in Chinese Mainland. Each of the foregoing committees consists of equal representation from us and BMS and operates under the oversight and decision-making authority of the joint steering committee.

Development and Commercialization Activities in the U.S.

In the U.S., SystImmune and BMS shall develop the Licensed Product in accordance with the global development plan as determined by the joint development committee, and share the relevant global development costs according to an agreed-upon percentage, with SystImmune's share being less than 50%. The joint development committee will review the global development plan for the purpose of considering appropriate amendments to the plan, which sets out, among other things: (a) the targeted indications, proposed clinical studies and related protocols; (b) the estimated timeline and budget; and (c) the allocation of development responsibilities between the parties. All development activities in the U.S. may be conducted jointly by BMS and SystImmune, primarily by either party, or outsourced to a third-party, as determined by the joint development committee based on each party's resources and capabilities with the intent of not duplicating efforts. The parties have

agreed on the initial global development plan and budget. Currently, SystImmune is designated by the joint development committee as the party responsible for conducting the ongoing global, multi-center, dose escalation, dose expansion Phase I clinical trial of the Licensed Product in the U.S.

Prior to the anticipated date of the regulatory approval for the Licensed Product in the U.S., SystImmune and BMS will, through the joint steering committee and joint commercialization committee, jointly develop and finalize a commercialization plan and budget which will govern the commercialization of the Licensed Product in the U.S. BMS will have the lead role for commercialization of the Licensed Product in the U.S. and SystImmune has a right to participate in certain commercialization activities in the U.S. that are allocated to it under the commercialization plan.

Manufacturing

For each party's development activities under the BMS Agreement, we are initially responsible for the manufacture and supply of the Licensed Product pursuant to a clinical supply agreement entered between us and BMS, which includes a supply schedule consistent with the global development plan and budget. We will manufacture such Licensed Product via our facilities in Chinese Mainland and will ship such Licensed Product to BMS's designated location in accordance with the terms under such clinical supply agreement. BMS has the right to request a transfer of the manufacturing technology. If BMS exercises the right, following completion of the technology transfer and subject to BMS's reasonable determination, BMS will be responsible for the manufacture and supply of the Licensed Product for the development activities in the U.S. and the ROW, and, upon our request and approval from the joint development committee, for the development activities in Chinese Mainland. In 2025, we completed such manufacturing technology transfer of the then-current manufacturing process. For commercialization in Chinese Mainland, we will be responsible for the manufacturing and supply of the Licensed Product, subject to certain rights retained by BMS and specified conditions. For commercialization in the U.S. and ROW, we will manufacture and supply a percentage of BMS's requirements of linker and payload for the Licensed Products; and BMS will be responsible for the manufacturing and supply of the finished Licensed Product subject to certain specified conditions, provided that the parties shall discuss in good faith using us as a source for supply.

Commercial Terms

Pursuant to the BMS Agreement, on March 7, 2024, we received a non-refundable and non-creditable upfront payment of US$800 million from BMS, which is not subject to any further conditions, and BMS is required to pay up to US$500 million in contingent near-term payments, which payment amounts are adjusted based on when each prescribed milestone is achieved. Specifically, SystImmune is eligible to receive a one-time nonrefundable milestone payment of US$250 million upon the initiation of the first Phase II or Phase III trial of the Licensed Product as 1L or 2L treatment in the U.S. on or before December 31, 2025 ("First Clinical Trial Milestone"), and another one-time nonrefundable milestone payment of US$250 million upon the initiation of the first Phase III trial of the Licensed Product as 1L treatment in the U.S. on or before December 31, 2026 ("Second Clinical Trial Milestone"). Such milestones were established through mutual agreement.

In this context, "initiation" means, with respect to a clinical trial, the first dosing of the first human subject in such clinical trial. Three global Phase II/III trials have been publicly disclosed and patient dosing started on or before December 31, 2025 (NCT06926868, NCT07100080 and NCT07106762). The first dosing of the first patient in any of these clinical trials qualified as a milestone event that would trigger the First Clinical Trial Milestone, and we have recognized as revenue in 2025 based on the BMS Agreement and relevant accounting policy. Based on the current pace of clinical progress for iza-bren and the anticipated market entry timetable, we reasonably anticipate that SystImmune will be eligible to receive the Second Clinical Trial Milestone. In

addition to the Second Clinical Trial Milestone, SystImmune is also eligible to receive up to an aggregate of US$7.1 billion contingent upon the achievement of certain specified regulatory and sales performance milestones for a total potential consideration of up to US$8.4 billion.

BMS is also required to pay SystImmune tiered royalties based on a percentage of aggregate annual net sales of the Licensed Product in ROW ranging from high single-digit to low double-digits, subject to certain customary reductions and a royalty floor. Such royalties are payable on a country-by-country basis from the first commercial sale of such Licensed Product in such country until the latest of (a) the expiration of all valid claims of certain licensed patents and joint patents covering the composition of matter of the Licensed Product in its entirety or its antibody portion in such country, (b) the tenth anniversary of the first commercial sale of such Licensed Product in such country, and (c) the expiration of regulatory exclusivity for such Licensed Product in such country. Under the BMS Agreement, we are required to pay BMS a single-tier royalty of a mid-single-digit percentage of aggregate annual net sales of such Licensed Product in Chinese Mainland. Further, under the BMS Agreement, SystImmune and BMS will share net profits/losses related to the sales of the Licensed Product in the U.S. according to certain agreed-upon percentages, with SystImmune's share being less than 50%, which percentage is higher than SystImmune's proportion of the shared development costs in the U.S.

Intellectual Property

Under the BMS Agreement, each party retains the sole and exclusive ownership of its respective intellectual property rights, including all intellectual property rights that are solely developed by such party, its affiliates or its and its affiliates' sublicensees under the BMS Agreement or are owned or otherwise controlled by such party, its affiliates of its or its affiliates' sublicensees independent of the BMS Agreement. The parties will jointly own any intellectual property rights that are developed jointly by the parties under the BMS Agreement. BMS has the first right to prosecute, maintain, defend and enforce against any infringement by a competing product, certain specified licensed patent rights and joint patents in the U.S. and the ROW, but we have the first right to prosecute, maintain, defend and enforce against any infringement by a competing product, any licensed patent rights and joint patents in Chinese Mainland.

Dispute Resolution

If there is any dispute between the parties (a) with respect to approval of the development of the Licensed Product in Chinese Mainland or ROW in a dose, formulation or indication that is not substantially similar to the dose, formulation or indication for which the Licensed Product is being developed under the development plan and budget or for which it receives regulatory approval in the U.S., subject to certain specified exceptions, we and BMS will have final decision-making authority in our respective territories, (b) with respect to any action proposed by us in Chinese Mainland or by BMS in ROW, for which the other party raises a concern that such proposed action has a material adverse impact on the development or commercialization of the Licensed Product in the U.S., such dispute shall be resolved by the expedited dispute resolution procedures set forth in the BMS Agreement, which is an expedited arbitration procedure where the parties will jointly select an independent, impartial and conflicts-free neutral to preside in the resolution of issues with specific timeframe for each step and deadlines as prescribed in the BMS Agreement; and (c) with respect to all other issues under the purview of the joint steering committee, if such issues cannot be resolved through a collaborative process, BMS shall have the final decision-making authority except for (i) amending the global development plan and budget to allocate activities to us without our consent, (ii) amending the aggregate budget under the global development plan and budget or the commercialization plan for the U.S. without our consent, (iii) developing any fixed dose combination product of the Licensed Product with another active ingredient controlled by BMS or its affiliates or sublicensees in the U.S. or certain European countries without our consent, and (iv) determining whether any action of a party is reasonably expected to have materially negative impact

on the development or commercialization of the Licensed Product in the other party's respective territory (collectively, the "Exclusion Matters"). For the Exclusion Matters, BMS may not exercise final decision-making authority without our consent.

Termination

Unless earlier terminated by either party, the BMS Agreement will expire on the later of (a) the expiration of all of our and BMS's royalty payment obligations in Chinese Mainland and ROW, respectively or (b) upon BMS's and SystImmune's mutual agreement to cease all exploitation of the Licensed Product in the U.S. Each Party has the right to terminate the BMS Agreement for the other party's certain specified uncured material breach or insolvency. We may terminate the BMS Agreement in its entirety if BMS or any of its affiliates and its and their sublicensees commences a legal action challenging the validity, enforceability or scope of any of certain specified patent rights that are owned or otherwise controlled by us. BMS may terminate the BMS Agreement, in its entirety or on a country-by-country basis, without cause by giving us at least 90 days' prior written notice, if such termination is before the first commercial sale of the Licensed Product in the U.S. or ROW, or at least 6 months' prior written notice, if such termination is thereafter, subject to our right to extend the effective date of such termination up to a specified time period. In addition, BMS may terminate the BMS Agreement immediately by written notice to us if such termination is necessary to protect the safety of patients due to a material safety issue.

RESEARCH AND DEVELOPMENT

Research and development is a fundamental pillar of our business and will continue to be critical to our future growth and our ability to remain competitive in the global biopharmaceutical market. In 2024, 2025 and the three months ended March 31, 2025 and 2026, our research and development expenses were RMB1,442.8 million, RMB2,513.7 million, RMB494.9 million and RMB694.8 million, respectively. In particular, our research and development expenses attributable to our Core Products were RMB745.8 million, RMB1,800.4 million, RMB326.5 million, and RMB488.9 million during the same periods, respectively, accounting for 51.7%, 71.6%, 66.0% and 70.4% of our total research and development expenses in the corresponding periods. Our in-house R&D capabilities revolve around our four core technology platforms: HIRE-ADC, GNC, SEBA and HIRE-ARC, which in turn serve as the foundation for our continued drug innovation. These platforms underpin our capabilities in ADCs and bispecific and multi-specifics and can be applied for a broad range of oncological indications and other diseases.

Our R&D Capabilities

Our R&D Facilities

We currently have three R&D facilities, namely our SystImmune R&D Center in Seattle, U.S., our Baili Pharm R&D Center and Baili-Bio R&D Center in Chengdu, Sichuan Province, PRC. These facilities collaborate closely to drive the development of innovative therapeutics from early discovery to clinical application, ensuring that our drug development remains robust, efficient, and geared towards meeting global healthcare needs.

Our SystImmune R&D Center in Seattle, U.S., with a gross floor area ("**GFA**") of approximately 1,300 sq.m., focuses on early-stage innovation, including antibody discovery, engineering, high-throughput screening, humanization and optimization. Our Baili-Bio R&D Center in Chengdu, with a GFA of approximately 3,500 sq.m., takes charge of the advanced development stages of innovative drug candidates, including preclinical pharmacology and toxicology evaluations, pilot-scale process development, quality research and clinical studies in China. Our Baili Pharm R&D Center in Chengdu, with a GFA of approximately 2,800 sq.m., focuses on the R&D of complex generic drug candidates, covering chemical formulations in anesthesia, parenteral nutrition, pediatric and anti-infectives drugs.

Our R&D Team

Aiming to validate innovative ideas efficiently and cost-effectively, we have structured our R&D capabilities across U.S. and China. As of March 31, 2026, we had an R&D team of 1,702 members across our offices in China and the U.S., accounting for approximately 52.0% of our total employees. As of the same date, 88.5% of our R&D staff focused on innovative drug discovery and development, while 11.5% focused on the R&D of generics and traditional Chinese medicines. Over 450 of them held a master's or higher degree, mainly in medical science, pharmacology, biology, and chemistry. Our R&D team covers the entire R&D cycle for innovative drugs, with members drawn from leading multinational companies and domestic biopharmaceutical companies, such as Merck, Eli Lilly, Pfizer, Novartis, Amgen, Sanofi, Hengrui and BeiGene, and renowned research institutes such as MD Anderson Cancer Center and Fred Hutchinson Cancer Center, as well as the FDA. The following table sets forth the composition of our in-house R&D team as of March 31, 2026.

R&D Department	Number	% of total
Preclinical Research	542	31.8
Clinical Development	1,147	67.4
Regulatory Affairs	13	0.8
Total	**1,702**	**100.0%**

Our R&D team is spearheaded by Dr. Zhu Yi, the visionary founder of our Group, who also serves as the chairman of the Board, the executive director, general manager and Chief Scientific Officer of our Company. With over three decades of experience in the healthcare industry, Dr. Zhu's academic journey began with a bachelor's degree in radio physics from Sichuan University (四川大學) in 1984, followed by a master's degree in biology from Fudan University (復旦大學) in 1987, and culminating in a doctoral degree in management from Sichuan University (四川大學) in 2008. Before establishing our Group, Dr. Zhu taught in the Department of Microbiology and Immunology at West China University of Medical Sciences (華西醫科大學) (currently known as West China Medical Center of Sichuan University (四川大學華西醫學中心)) from 1987 to 1990. In addition to Dr. Zhu Yi, core members of our innovative drug R&D team include Dr. Jonathan Cheng, CMO of SystImmune, who previously served as SVP and therapeutic area oncology head leading the late-stage clinical development of several key oncology treatments; Dr. Jahan Khalili, SVP and head of immune-oncology at SystImmune, with deep expertise in tumor immunology from MD Anderson Cancer Center; Dr. Zhu Hai, executive director and CTO & CDO of SystImmune, who previously served as a researcher at the FDA's Center of Drug Evaluation and Research; Mr. Zhuo Shi, executive director and GM of Baili-Bio, with over 14 years of experience in the biopharmaceutical industry and Dr. Wan Weili, deputy GM and GM of our Chengdu R&D Centers, who leads our ADC linker-payload platform and active pharmaceutical ingredient ("**API**")/formulation R&D. For further details of each person's biographies, please refer to "Directors and Senior Management."

Our U.S. subsidiary, SystImmune, has established a scientific advisory committee consisting of eight globally renowned oncology clinical experts, Dr. Hope Rugo, Dr. Sara Tolaney, Dr. Pasi Jänne, Dr. Helena A. Yu, Dr. Thomas Powles, Dr. Hossein Borghaei, Dr. Lillian Siu and Dr. Zev Wainberg. These advisors are leading physicians and researchers from premier academic medical centers in the United States, with deep expertise in BC, lung cancer and ADC-based therapeutics, which are the key therapeutic areas of our Core Products. They provide strategic guidance on our clinical development programs, including clinical trial design and clinical data interpretation. Notwithstanding the foregoing, all day-to-day R&D activities, including drug discovery, preclinical research, process development, clinical trial execution and regulatory submissions, are independently conducted and managed by our in-house R&D team.

Embracing a paradigm of project-oriented governance and matrix-style management, our R&D teams integrate their specialized knowledge to develop projects from conception to fruition under the leadership of project managers. Each R&D project begins with research and evaluation

conducted by key members from each technology platform, and will take into account factors such as clinical value, market trends, competitive landscape, and technological barriers, to select product candidates for approval. These proposals are then carefully scrutinized and assessed for approval by a committee comprising leaders from each technology platform. For projects that are approved for further development, we designate a project manager, who will establish and lead a core project R&D team comprising of members from pharmaceutical research, pharmacology and toxicology research, process development, and quality control within the technology platforms. This core team then develops detailed R&D plans and strategies to ensure the smooth execution of the R&D project in a time- and cost-efficient manner.

Collaboration with Third Parties

Collaboration with external R&D partners is a major component of our R&D strategy. Our strong in-house R&D capabilities, proven track record, and established manufacturing and commercial operations make us a preferred partner in the pharmaceutical market. We have joint R&D collaborations with universities and research institutions. We maintain strong cooperative relationships with a variety of trial sites (i.e., hospitals) and principal investigators ("**PIs**") to support our clinical trials for different indications at various stages. Our medical and clinical trial team is tasked with formulating trial protocols and selecting and engaging trial sites and PIs to carry out these trials. The PIs, who are generally physicians or researchers at the trial sites, lead the clinical trial activities for our drug candidates.

We do not have direct agreements with PIs other than confidentiality agreements to ensure they meet confidentiality obligations. In accordance with the laws and regulations, we enter into clinical trial cooperation agreements with the clinical trial sites that the PIs belong to and settle the fees and expenses with those sites. The below sets forth key terms of our framework agreements with clinical trial sites on clinical trial cooperation:

- ***Trial Materials***. We furnish the clinical trial sites with trial protocols and other trial-related documents, investigational drugs, consumables, and necessary research funding.

- ***Monitoring and Compliance***. We appoint qualified monitors to oversee the adherence to Good Clinical Practice ("**GCP**") standards, review protocol deviated cases, and review clinical data to protect the safety of subjects and ensure the integrity of trial results.

- ***Qualification of PI***. The clinical trial site is responsible for reviewing the qualifications of PIs and their research team to ensure their qualification.

- ***Data Management and Reporting***. The clinical trial site shall organize all related trial documents and provide us with accurate case report forms and other required written materials. These materials must comply with the clinical research protocol, national regulations, and our requirements as stipulated in the agreement.

- ***Costs and Funding***. We typically cover the expenses for trial participants, typically include the costs of medical examinations and treatment, and compensation for time and effort to participants, such as their meals and travel costs.

- ***Confidentiality***. The clinical trial site is obliged to maintain the confidentiality of the agreements and any trial-related materials.

- ***Intellectual Property***. We retain full intellectual property rights and associated interests over all case report forms, original records, trial content and results, and any other technical data generated during the clinical trial at the clinical trial site. The clinical trial site is prohibited from using or transferring these materials without our explicit permission.

- ***Insurance and Liability***. We provide clinical trial liability insurance for participants, as mandated by law. In the event of trial-related injuries, both parties shall share responsibility for economic compensation and other consequences based on the degree of fault.

- ***Termination***. Typically, we have the right to terminate the clinical trial provided we give the prior written notice to the clinical trial site.

While we primarily rely on our in-house capabilities in managing and conducting preclinical and clinical studies of our pipeline drug candidates, in line with industry practice, we also engage domestic and international contract research organizations ("**CROs**") and site management organizations ("**SMOs**") to support our internal team.

Our in-house team conducts most of our preclinical drug R&D activities and clinical development activities, while engaging contractors for tasks that are either not cost-effective to manage internally or require specialized licenses and qualifications. In the preclinical stage, we internally develop our drug candidates from discovery to IND submission. We mainly engage preclinical CROs to conduct toxicology studies on animals, which require specific licenses and qualifications, along with certain testing activities related to CMC. In the clinical stage, our internal clinical development team handle most of the critical functions of a clinical trial, including the trial design, clinical research monitoring, data monitoring and analysis, as well as decision-making, thereby ensuring the quality and efficiency of our clinical trials. We mainly involve SMOs to coordinate patient screening and enrollment and support the day-to-day site management, and also engages some contractors to test clinical samples. Additionally, we engaged clinical CROs in the U.S. to provide a comprehensive suite of services to support the implementation and management of our ongoing clinical trials. At the trial's inception, we had limited INDs abroad and were in the early stage of establishing our clinical operations capacity in the U.S. As the number of international trials has grown, we have progressively enhanced our in-house clinical research capabilities in the U.S.

We have established a comprehensive mechanism for the selection, evaluation, and management of these partnerships, ensuring compliance while reducing R&D costs and enhancing the efficiency of our development efforts. Based on the service requirements of each project, we typically select at least two or more CROs to participate in competitive bidding and negotiations, and have alternatives in place for each service supplier. We generally enter into framework agreements with CROs and we have executed statements of work on a project basis. The below sets forth key terms of our framework agreements with CROs:

- ***Service***. The CROs provide us with specified services related to product development, including clinical trial management, patient recruitment, data collection and analysis, monitoring and reporting, among others, according to the project requirements agreed in advance.

- ***Term***. The CROs shall deliver their product development services at an acceptable quality within the specified timeframe, typically ranging from one and a half years to five years.

- ***Payments***. We typically pay CROs an initial payment upon the execution of the agreement and make subsequent payments contingent upon the CRO meeting specific project milestones. We generally reconcile all payments against the deliverables provided by the CRO at the conclusion of the project.

- ***Intellectual property rights***. All intellectual property rights arising from the product development project and any derivative intellectual property rights therein shall be owned by us.

- ***Confidentiality***. The CROs shall comply with Good Clinical Practice (GCP) guidelines to protect participant privacy and shall not disclose any trial-related information, including trial plans, progress reports, or related data, to unauthorized personnel or entities, as stipulated in the contract.

- ***Quality assurance***. In the event of any issues, the CRO shall be required to implement corrective actions within a specified timeframe, ensuring compliance with GCP guidelines and the predefined acceptance standards of the project.

- ***Allocation of liability***. CROs must adhere to all applicable laws, regulations, and industry standards throughout the research process. Generally, CROs shall indemnify us losses resulting from their negligence, intentional misconduct or breach of its obligations under the agreement.

MANUFACTURING

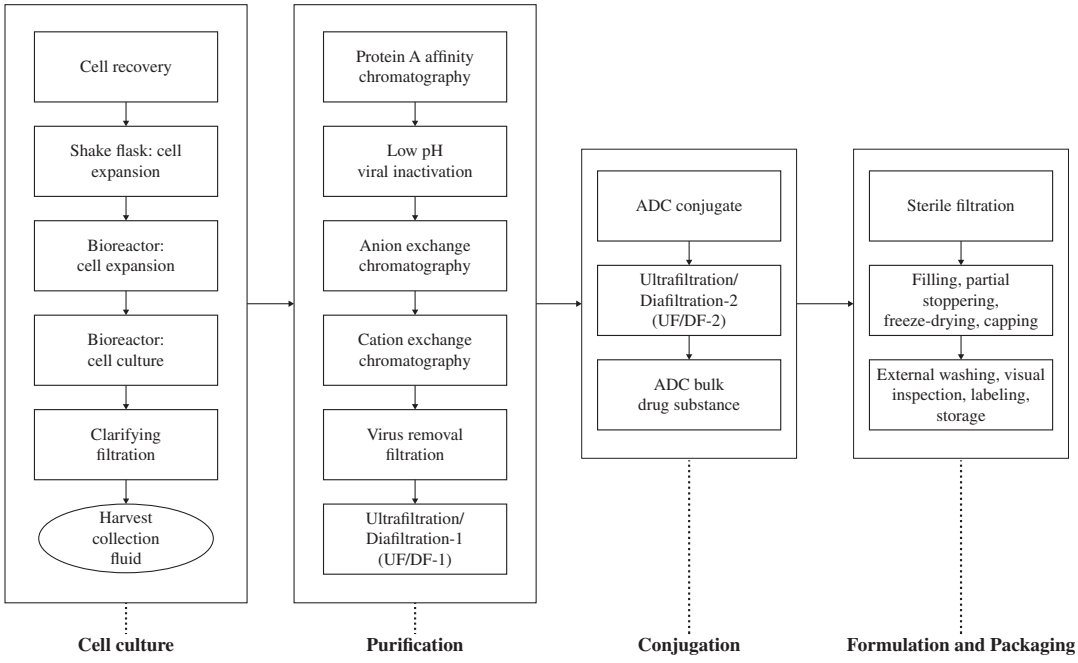
Manufacturing Process

We manufacture all of our innovative drug candidates as well as our generic drugs and traditional Chinese medicines on our own, which are in a variety of dosage forms, including injections, tablets, capsules, and granules. As part of our manufacturing operations, we continuously devise strategies to efficiently manage costs, maintain quality standards, and ensure consistent market supply.

We operate different production processes for our pharmaceutical products and APIs.

Innovative Biologics

Our biologics drug candidates under development mainly include ADCs, bispecific and multi-specific antibodies. The typical production process for ADCs is illustrated in the following flowchart:



Generic Drugs and Traditional Chinese Medicines

We manufacture our marketed drug products in a variety of dosage forms, each following Good Manufacturing Practice ("**GMP**")-compliant production processes:

- ***Fat emulsion injections.*** Including propofol medium and long chain fat emulsion injection, propofol injectable emulsion, and medium and long chain fat emulsion injection, the production process primarily involves weighing and dispensing of raw materials, emulsification and homogenization, sterile filtration, filling and sealing, and sterilization, visual inspection, labelling and packaging.

- ***Injectable products.*** Including dexmedetomidine hydrochloride injection, the production process primarily involves preparation of drug solution, sterile filtration, filling and sealing, sterilization, visual inspection, labelling and packaging.

- ***Lyophilized powder injection products.*** The production process primarily involves preparation of drug solution, sterile filtration, filling, vacuum freeze-drying, capping, visual inspection and packaging.

- ***Granules, tablets, and capsules.*** Including astragalus granules and ornidazole capsules, the production process primarily involves preprocessing and ingredient preparation of raw and auxiliary materials. For granules, the process proceeds through granulation, drying, whole granule classification, bulk mixing, testing and packaging. For tablets, the process additionally involves tableting and coating after granulation. For capsules, the process involves capsule filling after ingredient preparation, followed by encapsulation, testing and packaging.

- ***APIs.*** The majority of the APIs used in our drug products are obtained through our own chemical synthesis processes, primarily involving synthesis, refinement, dispensing and packaging.

Manufacturing Facilities

We currently have five manufacturing facilities, housing a total of 29 production lines for our major approved drugs. Our Baili-Bio Base is dedicated to the production of innovative biologics, while our Guorui Base, Baili Base, Hiatt/Jingxi Base and Tianze Base are primarily used for the production of generic drugs and traditional Chinese medicine products. We currently own the major production equipment used in our manufacturing process. We strictly carry out maintenance and repair work in compliance with applicable requirements and we replace or upgrade our production equipment when necessary to enhance productivity. During the Track Record Period and up to the Latest Practicable Date, we obtained production licenses for all of our production bases and marketing approvals for each of our marketed products.

Innovative Biologics

We have established several production workshops for our innovative drugs in our Baili-Bio Base in Chengdu, Sichuan Province, which forms a robust foundation for the commercial production of our innovative drugs and our ongoing clinical studies. As of March 31, 2026, our manufacturing team focusing on the production of innovative biologics in our Baili-Bio Base consisted of over 500 employees. With a GFA of approximately 36,000 sq.m., our Baili-Bio Base houses various workshops, covering the full cycle of cell culture, antibody purification, ADC conjugation, filling, lyophilisation and packaging.

We have established cell culture and purification workshops for the production of high-quality antibodies. Our cell culture workshop features six 2,000 L bioreactors and one 1,000 L bioreactor for large-scale cell growth, with single-use bioreactors that reduce cross-contamination between batches. Our purification workshop houses protein purification chromatography systems and ultrafiltration equipment for efficient antibody separation and purification.

Our ADC conjugation workshop features a 1,000 L conjugation reactor and automated conjugation systems for efficient ADC conjugation, together with ultrafiltration and isolator systems. Our facility is designed to produce more than 100 batches of ADC bulk drug substance annually.

We have two preparation production lines for final product filling and lyophilization. With advanced, fully automated production equipment such as automatic vacuum freeze dryer (自動真空冷凍乾燥機), standing ultrasonic cleaning machine (立式超聲波清洗機), and tunnel sterilization dryer (隧道式滅菌乾燥機), we possess advanced large-scale production capabilities for lyophilized powder injections. The annual production capacity of our Baili-Bio Base is approximately 1,000 thousand bottles of final products, including approximately 500 thousand bottles dedicated to iza-bren, sufficient to support commercial-scale production of our innovative drugs as well as approximately 100 clinical trials, depending on the candidate drug being produced. We are confident that with the current production capacity of our Baili-Bio Base, we are prepared to support IND applications, clinical trials and commercialization for our Core Products and other pipeline drug candidates.

Our commercialized innovative drug, iza-bren, is available as a lyophilized powder for injection in a specification of 120 mg per vial. Iza-bren is currently manufactured at our Baili-Bio Base, which serves as the production facility for the commercial supply of iza-bren worldwide.

To further support the clinical trials and commercialization of our innovative drugs, we are expanding our Baili-Bio Base and plan to initiate technical upgrade of our Jingxi Base. In addition, we are planning the construction of two new production facilities: (i) a dedicated production facility for ARCs in Chengdu, and (ii) an integrated biotech campus in Shanghai with a planned site area of approximately 90,000 sq.m. for R&D and manufacturing. During the Track Record Period, we engaged one CDMO with requisite qualifications for handling and manufacturing radioactive pharmaceutical products solely for the manufacture of our ARC drug candidates.

Generic Drugs and Traditional Chinese Medicines

We have strategically established an "API — finished pharmaceutical products" manufacturing platform for generic drugs and traditional Chinese medicines through synergy among four facilities: Hiatt/Jingxi Base for intermediates and chemical APIs, Guorui Base for injection products and oral preparation products, Baili Base for oral solid preparations and freeze-dried powder injection products and Tianze Base for oral solid preparations. These production facilities are fully equipped with advanced automated equipment such as boiling granulator (沸騰制粒機), liquid filling and capping machine (液體灌裝旋蓋聯體機), standing ultrasonic washing machine (立式超聲波清洗機), tunnel sterilization dryer (隧道式滅菌乾燥機), high-pressure homogenizer (高壓均質機) and YK-160 Pharmaceutical Swing Pellet Granulator Machine (YK160搖擺式顆粒機), and double layered glass reactor (雙層玻璃反應釜).

As of the Latest Practicable Date, our manufacturing facilities for generic drugs and traditional Chinese medicines occupied an aggregate site area of approximately 174,341 sq.m. and had an aggregate GFA of approximately 90,142 sq.m, housing a total of 29 production lines for our major approved drugs. The following table sets forth a summary of our manufacturing facilities for our generic drugs and traditional Chinese medicines as of the Latest Practicable Date.

Facility	Location	Site Area	GFA	Major Products Produced
		(sq.m.)	*(sq.m.)*	
Guorui Base	Leshan, Sichuan Province	77,389	50,086	Propofol injectable emulsion, dexmedetomidine hydrochloride injection, propofol medium and long chain fat emulsion injection, medium and long chain fat emulsion injection, etomidate medium/long chain fat emulsion injection and structural fat emulsion injection
Baili Base	Wenjiang, Sichuan Province	60,000	16,482	Astragalus granule, ornidazole capsule, chaihuang granule, glucose electrolyte effervescent tablet, ribavirin granule, racecadotril granule, sevoflurane for inhalation and guanfacine hydrochloride tablet
Hiatt/Jingxi Base	Qionglai, Sichuan Province	33,349	19,478	Propofol crude drugs, sevoflurane crude drugs, sevoflurane API, etomidate API, structural oil, guanfacine hydrochloride API, as well as certain APIs for iza-bren
Tianze Base	Lhasa, Xizang Autonomous Region	3,602	4,096	Glucose electrolyte effervescent tablet and enalapril maleate oral solution

The following table sets forth the designed production capacity, actual production volume and utilization rates of the production lines which are used in these facilities by formulation types as of the dates and for the periods indicated.

		As at/For the year ended December 31,						As at/For the three months ended March 31,		
		2024			2025			2026		
Production lines	Unit	Designed production capacity[1]	Production volume[1]	Utilization rate (%)[2]	Designed production capacity[1]	Production volume[1]	Utilization rate (%)[2]	Designed production capacity[1]	Production volume[1]	Utilization rate (%)[2]
Large Volume Injections[3]	'0,000 vials	900	1,187	131.9%[3]	900	1,238	137.6%[3]	225	252	112.0%[3]
Small Volume Injections[4]	'0,000 vials	2,000	411	20.5%[4]	2,000	637	31.8%[4]	500	70	14.1%[4]
Capsules	'0,000 pills	15,750	655	4.2%	15,750	637	4.0%	756	121	16.0%[7]
Tablets	'0,000 tablets	14,000	418	3.0%	14,000	1,122	8.0%[5]	1,434	189	13.2%[7]
Granules	'0,000 bags	66,400	29,930	45.1%	66,400	13,116	19.8%[6]	12,445	3,318	26.7%[7]

Notes:

(1) Designed production capacity relates to the designed annual production capacity of our production facilities in operation at the end of the period, which may not be a constant variable throughout the period. Our annual production volume equals to the quantity of finished drug products stored in our warehouse after production during the indicated period.

(2) Utilization rates in 2024 and 2025 are calculated as the production volume for the year divided by the production capacity for the years. Utilization rates for the three months ended March 31, 2026, are calculated as the production volume for the period divided by a quarter of the total production capacity for the year.

(3) Large volume injections refer to injections with a specification of 50ml, 100ml, 250ml and 500ml. Following the inclusion of Leweijing's 50ml:0.5g specification in the ninth batch of the national VBP scheme at the end of 2023, demand for this specification increased significantly in 2024 and continued into 2025 and the three months ended March 31, 2026, driven by the sustained procurement volumes under the VBP scheme. As a result, our production mix shifted toward smaller-volume vials (50ml) and away from larger-volume specifications throughout these periods. Since our designed production capacity is measured in number of vials based on the historical specification mix, the same total volume of output, when filled into smaller vials, yields a greater number of vials than the designed capacity assumed, resulting in utilization rates exceeding 100% in 2024, 2025 and the three months ended March 31, 2026.

(4) Small volume injections refer to injections with a specification less than 50ml. The utilization rate of our small volume injection production line increased from 20.5% in 2024 to 31.8% in 2025, primarily driven by increased market demand for etomidate medium/long chain fat emulsion injection. The utilization rate subsequently decreased from 31.8% in 2025 to 14.1% in the three months ended March 31, 2026, primarily due to a subsequent decline in market demand for this product, resulting in minimal production.

(5) The utilization rate of our tablet production line increased from 3.0% in 2024 to 8.0% in 2025, primarily driven by increased market demand for Leyeping and Pujikang.

(6) The utilization rate of our granule production line decreased from 45.1% in 2024 to 19.8% in 2025, primarily due to decreased market demand for ribavirin granule, resulting in lower production volume of this product.

(7) The utilization rates of our capsule, tablet and granule production lines were relatively low in 2024 and 2025, reflecting changes in market demand for the relevant products during these periods. In response, we decommissioned certain production workshops at our Baili Base commencing in January 2026, which reduced the designed annual production capacity for capsules from 157.5 million pills to 7.6 million pills, for tablets from 140 million tablets to 14.3 million tablets, and for granules from 664 million bags to 124.5 million bags. As a result, the utilization rates of these production lines increased in the three months ended March 31, 2026.

We meticulously monitor our production capacity in real-time and dynamically make adjustments based on current conditions and future projections. We also plan to establish new production lines to meet the ever-evolving market demand for our generic drugs and traditional Chinese medicines as needed.

Supply Chain Management

We have a dedicated procurement team overseeing our supply chain management in alignment with GMP standards. We have stringent supplier selection procedures in place, requiring suppliers to hold all necessary licenses and permits and to pass our assessment in terms of product quality, corporate management, reputation and pricing. Only suppliers that pass our comprehensive evaluation, which includes on-site audits, document review and sample inspection are included in our qualified supplier list, from which we source our raw materials. We routinely assess supplier performance and remove those that fail to meet our requirements. For established products with stable demand, our procurement team makes annual tender procurement plans based on material requirements from the production department. For new products and major raw materials with significant price fluctuations, the procurement team manages procurement in response to demands from the production or research departments. During the Track Record Period, we did not experience any material shortage of or delay in the supply of raw materials. We believe that adequate alternative sources for such supplies exist, and we have developed alternative sourcing strategies for these supplies.

SALES AND MARKETING

Commercialization of our Innovative Drugs

As of the Latest Practicable Date, iza-bren had received NDA approvals from the NMPA for the treatment of NPC in June 2026 and ESCC in July 2026, while the NDA application for TNBC had been accepted by the NMPA. The year 2026 marks the inaugural year of our innovative drug commercialization. To support the commercialization of iza-bren in Chinese Mainland, we are building a dedicated commercialization team with specialized expertise in oncology that operates independently from the sales and marketing team for our generic drugs and traditional Chinese medicine products. This team encompasses key commercial functions, including compliance, commercial operations, government affairs and market access, medical affairs and marketing, and is responsible for delivering specialized medical information and conducting academic promotion to healthcare professionals at target hospitals, which are primarily Class III hospitals and leading cancer centers where the target patient populations for iza-bren's approved indications are concentrated. As of the Latest Practicable Date, this team comprised over 600 professionals with specialized expertise and relevant experience in oncology. As of the same date, all of our commercialization professionals for iza-bren are in-house employees, and we have not engaged any contract sales organizations ("**CSOs**"). We believe that the oncology commercialization expertise we are building through the launch of iza-bren will provide a scalable foundation to support the future commercial launch of additional innovative drug candidates from our pipeline and advance our growth into a globally competitive, commercial-stage biopharmaceutical company.

As of the Latest Practicable Date, we had grown iza-bren's commercial coverage to span 30 provincial-level regions and 161 cities across Chinese Mainland, with access through over 450 direct-to-patient pharmacies located in proximity to major hospitals and leading cancer centers. We are actively pursuing hospital admissions to further broaden patient access.

Sales and Marketing of Our Generic Drugs and Traditional Chinese Medicine Products

During the Track Record Period, we generated a portion of our revenue from the sales of 31 approved generics (covering a wide range of therapeutic areas such as anesthesia, parenteral nutrition, pediatric and anti-infective drugs) and traditional Chinese medicine products. We generate demand for our generic drugs and traditional Chinese medicine products mainly through our in-house sales and

marketing team, which conducts comprehensive marketing activities to promote our products. In addition, we have built strong collaborations with local promoters and distributors to enhance the brand recognition and market acceptance of our products.

In-House Sales and Marketing Team

We have established a comprehensive sales and marketing system that spans over 30 provinces and 200 cities across China, which ensures that our products reach all major markets as well as urban, county, and township areas. As of March 31, 2026, our dedicated sales and marketing team for generic drugs and traditional Chinese medicine products comprised of 149 experienced professionals with strong sales capabilities and experience to support systematic planning and efficient network operations. Our sales and marketing team is responsible for product positioning research, market planning, business policy formulation, academic education activities, product tendering, price maintenance, sales contract management, and all other critical supporting functions. We regularly provide in-house and external trainings to enhance the industry knowledge and marketing skills of our sales and marketing team.

Marketing Activities

We organize, sponsor and participate in a wide variety of academic conferences, seminars and symposia to enhance our brand recognition. We also engage in routine academic discussion with medical experts and other healthcare professionals in our target therapeutic areas. In addition, collaborating with leading academic institutions and research organizations to conduct clinical trials increases our visibility.

To supplement our in-house sales and marketing capabilities, we engage third-party promoters to collect market data and provide research and consultation services, which effectively guides our future product promotion plans and resource allocation for market expansions. Further, we continuously enhance and refine our marketing strategies for generic drug products to align with national policies and regulatory requirements. Our robust marketing infrastructure and dedicated team efficiently cater to diverse market segments, including both the prescription drug market and OTC drug market where we reinforce our established product brands and increase the market penetration of our approved products.

We carry out the marketing activities in strict compliance with relevant laws and regulations in PRC. We have never engaged in any form of payment or commercial bribery to any medical institutions, regulatory agencies, or healthcare professionals through organizing or sponsoring academic conferences, seminars, or other promotional activities. Furthermore, we have never paid any fees to other entities or individuals through promotion service providers. During the Track Record Period and up to the Latest Practicable Date, neither we nor any of our directors or senior management have been penalized by regulatory authorities for commercial bribery, nor have they been investigated by the PRC authorities or found guilty by the PRC courts for such conduct. Also, there are no legal proceedings related to commercial bribery involving us. We believe anti-corruption campaigns targeting China's medical sector launched by the PRC authorities will not have a significant adverse impact on us.

Sales

We generate substantially all of our revenue from the sales of generic drugs and traditional Chinese medicine products primarily by selling our products to distributors who, in turn, sell our products to hospitals, pharmacies and other medical institutions. We also sell directly to retail pharmacy chains. Our sales strategy is in line with the industry norm in the pharmaceutical industry, according to CIC. The following table sets forth a breakdown of our revenue from the sales of generic drugs and traditional Chinese medicine products by distribution channels for the periods indicated:

	Year ended December 31,				Three months ended March 31,			
	2024		2025		2025		2026	
	Amount	%	Amount	%	Amount	%	Amount	%
	(RMB in thousands, except for percentages)				*(unaudited)*			
Distributors	483,783	99.4	375,600	98.8	59,341	98.1	91,292	99.3
Direct sales to retail pharmacies	2,976	0.6	4,475	1.2	1,164	1.9	689	0.7
Total	**486,759**	**100.0**	**380,075**	**100.0**	**60,505**	**100.0**	**91,981**	**100.0**

Distributors

We primarily sell our generic drugs and traditional Chinese medicine products through third-party distributors, who are our direct customers and are responsible for subsequently selling and delivering our products to hospitals, pharmacies, and other medical institutions. We believe our distribution strategy helps extend our coverage in a cost-effective manner while retaining proper control over our distribution network and marketing and promotion activities.

Distribution Network

Our distributors include hundreds of nationally known pharmaceutical distributors with widespread sales presence across the country, as well as regional distributors with deep market penetration within specific geographic areas, all of which are located in China. As of the Latest Practicable Date, our distribution network comprised of over 800 distributors across more than 30 provinces and over 200 cities. This extensive network and close collaboration with distributors have cultivated a dynamic, open marketing system that effectively stimulates cooperation and sales, ensuring strong sales capabilities across various regional and local markets. In 2024, 2025 and the three months ended March 31, 2025 and 2026, sales to our distributors amounted to approximately RMB483.8 million, RMB375.6 million, RMB59.3 million and RMB91.3 million, which approximately accounted for 99.4%, 98.8%, 98.1% and 99.3% of our revenue from the sale of pharmaceutical products, respectively.

To the best knowledge of our Directors, all of our distributors during the Track Record Period and up to the Latest Practicable Date were independent third parties; and none of our distributors transacted with us during the Track Record Period and up to the Latest Practicable Date are controlled by our former or current employees, uses our brand or name, or has received any material advance or financial assistance from us.

The following table sets forth the movement of the number of our distributors for the periods indicated below.

	Year ended December 31,		Three months ended March 31,
	2024	2025	2026
Number of distributors at the beginning of the period	1,742	1,449	1,218
Addition of new distributors[1]	345[3]	270[3]	71[3]
Termination of existing distributors[2]	638[5]	501[5]	508[5]
Net increase/(decrease) in distributors	(293)	(231)	(437)
Number of distributors at the end of the period	1,449	1,218	781

Notes:

(1) New distributors refer to distributors who (i) had at least one transaction with us in the relevant period; and (ii) did not have any transaction with us in the immediately preceding calendar year.

(2) Terminated distributors refer to distributors who (i) did not have any transaction with us in the relevant period; and (ii) had at least one transaction with us in the immediately preceding calendar year.

(3) The distribution agreements we enter with distributors generally have a term of one year. In 2024, 2025 and the three months ended March 31, 2026, distributors who had at least one transaction with us in the respective year and did not have any transaction with us in the immediately preceding year amounted to 345, 270 and 71, respectively, primarily due to our increasing need to engage distributors mainly for distributing, in line with the growth of market demand, our major products Leweijing, Xinbolin, astragalus granule and sevoflurane for inhalation, as well as other products such as structural fat emulsion injection and dexmedetomidine hydrochloride and sodium chloride injection.

(4) We expect that certain distributors who had at least one transaction with us in 2025 but did not have any transaction with us in the three months ended March 31, 2026 will work with us during the remainder of the year.

(5) In 2024, 2025 and the three months ended March 31, 2026, distributors who did not have any transaction with us in the respective year and had at least one transaction with us in the immediately preceding year amounted to 638, 501, and 508, respectively, primarily due to (i) the inclusion of the compound of Leweijing in the ninth batch of national VBP scheme in November 2023, under which Leweijing is mainly supplied for seven provinces, (ii) the suspension of online listing of medium and long chain fat emulsion injection on the centralized procurement platforms in certain provinces, and (iii) the discontinuation of cooperation for certain specifications of our generic drugs and traditional Chinese medicines in certain distribution channels.

Distributor Management

Each business division of our sales and marketing team is responsible for the overall management of distributors of the specific products within its responsibility, ranging from selecting, monitoring, reviewing and managing risks associated with our distributors. We choose our distributors based on their demonstrated distribution capabilities, knowledge of their respective markets, financial stability, creditworthiness, and operational scale. All distributors must hold the necessary licenses and permits for pharmaceutical sales and distribution. Additionally, our distributors are required to comply with the latest GSP standards for cold-chain storage and transportation, ensuring that our products are delivered safely and promptly to the targeted medical institutions and pharmacies.

Terms of Distribution Agreements

We have a seller-buyer relationship with our distributors under the buy-out sale model. We retain no ownership over the products that we sell to them, and all significant risks and rewards associated with these products are transferred to them upon delivery to and acceptance by them. We enter into distribution agreements with our distributors. Individual sales contracts or purchase orders are generally separately entered into or placed for each purchase. The following sets forth salient terms of our distribution agreements:

- ***Term.*** The typical duration of distribution agreements is one year.

- ***Designated distribution area.*** Distributors are generally not allowed to sell or distribute our products outside of their designated distribution areas.

- ***Exclusivity.*** Distributors are granted the distributorship of specified certain types of products in their designated distribution areas generally on a non-exclusive basis.

- ***Sales target and minimum purchase requirement.*** Our agreements with distributors generally do not specify an agreed annual sales target or minimum annual purchase amount.

- ***Resale price management.*** We generally do not control the prices at which our distributors resell our products to their customers.

- ***Inventory level.*** We generally do not require our distributors to maintain a minimum inventory level. We have the right to take stock of distributors' inventory of the products sold by us from time to time.

- ***Return of products.*** Our distributors are required to inspect the products on delivery. Returns and exchanges are generally not allowed except for defective products or damages.

- ***Access to information.*** We require major distributors to provide us with access to information at our request, usually on a monthly basis, including providing us with sales data of our products or with access to such information through their information technology system.

- ***Credit terms.*** We generally grant our major distributors credit terms of 30 to 120 days, with longer terms granted to selected distributors with whom we have built a strong business and financial track record. We also require prepayments for product deliveries to our distributors in certain instances.

- ***Confidentiality.*** Both parties have non-disclosure obligations and undertake to only use each other's trade secrets and other business information to the extent necessary and not to disclose such trade secrets or other business information to any third party.

- ***Termination.*** We may terminate the distribution agreements in the event of, among others, (i) any material breach by our distributors, such as sales outside of their designated distribution areas and providing falsified sales data; or (ii) any other breach by our distributors that is not remedied within a prescribed time-period.

Prevention of Cannibalization and Channel Stuffing

We believe that our sales correspond to actual market demand and therefore our products are at low risk of channel stuffing in our distribution network, because:

(i) We generally do not have mandatory sales targets for distributors, which we believe encourages distributors to order based on actual market demand and sales forecasts.

(ii) We adopt a sales model that transfer the full ownership of the goods at the time of acceptance, and normally there are no return rights for unsold inventory during the contract term, except for product defects, incorrect deliveries, damages, or policy-related factors. This model shifts the responsibility and risk of unsold inventory to the distributors. Since their capital is tied up in the inventory, the distributors are incentivized to order based on actual sales demand, thus reducing holding costs and the risk of obsolescence. Our cumulative amount of actual product return for the revenue recognized during the Track Record Period, as measured subsequent to the Track Record Period and up to June 30, 2026, was RMB7.2 million, accounting for 0.8% of the total revenue from the sales of pharmaceutical products, which was in line with prevailing industry practices as advised by CIC.

(iii) During the Track Record Period, a substantial majority of our pharmaceutical products were sold through distributors, primarily via VBP schemes and online listing on the centralized drug procurement platforms, which together provided a high degree of transparency and certainty in sales volume and pricing. Consequently, the role of our distributors for these products was primarily logistical, focusing on delivering products according to the orders placed by public hospitals, which reduced the incentive for distributors to overstock.

We have implemented a multifaceted approach to minimize the risk of sales cannibalization among our distributors. We enforce geographic limitations, which clearly specify the designated distribution areas in our distribution agreements for each of our distributors and forbid sales beyond these zones. Together with the detailed information regarding the flow of monthly sales of our products through our major distributors, we diligently oversee their sales to end customers or sub-distributors (if any), and spot any abnormalities in a timely manner. Once we detect such sales anomalies, including cross-regional or cross-channel sales, we will immediately require our distributors to halt all sales and shipments, and return their stock to us. If, under these circumstances, distributors continue to sell the products externally, we will impose penalties for the unauthorized sales, including financial sanctions and potential termination of distribution agreements.

We have also adopted various measures to avoid channel stuffing. According to our distribution agreements, product returns are not allowed unless there is a product quality issue, which helps us to minimize channel stuffing risk. We regularly sample for different products and review information including sales and/or inventory data from our distributors, and may request further information if we identify any irregularities. We also consider purchase volumes, historical data, regulatory changes, and other market factors to monitor our product sales. Further, we actively adjust our sales strategy and geographic or product coverage of each distributor based on market demand and each distributor's capacity. During the Track Record Period and up to the Latest Practicable Date, we did not notice any unusually large procurements that were inconsistent with distributors' past practices, nor did we notice any abnormally high inventory level of our distributors.

Anti-corruption and Anti-bribery Measures

Distributors are subject to anti-corruption and anti-bribery obligations pursuant to the terms of our distribution agreements, under which distributors (i) are required to comply with PRC laws and regulations, including anti-corruption and anti-bribery laws and regulations; and (ii) shall bear integrity obligation. See "— Risk Management and Internal Controls."

Implication of and Compliance with the "Two-Invoice System"

We are subject to the "Two-Invoice System" in China, under which invoices are issued by drug manufacturers to drug distributors on a one-off basis while invoices are issued by drug distributors to medical institutions on a one-off basis. Public medical institutions are required to adopt the "Two-Invoice System," while private medical institutions are encouraged but not required to adopt the "Two-Invoice System." Pharmaceutical manufacturers and distributors who fail to implement the two-invoice system may be disqualified from attending future bidding events or providing distribution for hospitals and blacklisted for drug procurement practices.

In our agreements with distributors, we specify the regions and types of end-customer, such as hospitals, pharmacies and clinics, to which each distributor is authorized to sell our products. Under the circumstances where public hospitals are the end-customers, which are subject to the Two-Invoice System, we strictly comply with the "Two-Invoice System" and our distributors can only sell our products directly to public hospitals without involving any sub-distributors, as required by the relevant policy. Some of our prescription drug products, such as Leweijing, Leweitai and Tianze, are predominantly sold to public hospitals and therefore such sales are subject to the Two-Invoice System.

Under the circumstances where the end-customers are not public hospitals but pharmacies, clinics and private hospitals, since the Two-Invoice System is not required to be adopted, we do not prohibit our distributors to engage sub-distributors. Some of our distributors may use sub-distributors to extend the product reach due to the typically large number and scattered distribution of pharmacies, clinics and private hospitals, which is in line with the industry norm, according to CIC. For some of our non-prescription drug products, such as astragalus granule, the majority of end-customers are private hospitals, pharmacies and other medical institutions, which are not subject to the Two-Invoice System. Generally, we do not have contractual relationships with

sub-distributors engaged by our distributors, who hold primary supervisory responsibilities over their respective sub-distributors. We enter into agreements with a small number of sub-distributors, whom we consider responsible for distribution in key locations while handling a substantial quantity of sales. We entered into agreements with 188, 123 and 98 sub-distributors in 2024, 2025 and the three months ended March 31, 2026, respectively.

We have implemented a series of internal control measures to monitor the implementation of the Two-Invoice System across different areas, ensuring our ongoing adherence to relevant rules, regulations and policies. For example, we provide training to our management and sales and marketing teams to enhance their understanding of the Two-Invoice System and related regulations, and we require our sales and marketing teams to adjust distribution strategies promptly according to the latest implementation status of the Two-Invoice System. We also closely communicate with distributors to gain insight into the distribution of products. Generally, we request the identities of their end-customers or sub-distributors from our major distributors monthly, and we typically require those with sub-distributors to provide us with the identities of end-customers of their sub-distributors as well. Should we detect any violations, we will enforce stringent penalties, including but not limited to suspension of the distributor's contract, liquidated damages, and potential legal action.

Our Directors confirm that during the Track Record Period and up to the Latest Practicable Date, we (i) had not been deemed to have violated or circumvented any law, regulations, rules or policies in relation to the "Two-Invoice System", (ii) had not been disqualified from participating in public tendering processes in any province, (iii) were not subject to any administrative fines or penalties by the competent authorities in relation to the "Two-Invoice System", and (iv) had not received any warning or notice from any competent authorities in relation to the compliance of the "Two-Invoice System."

Direct Sales to Retail Pharmacies

For around 1% of our revenue from sales of generic drugs and traditional Chinese medicine products during the Track Record Period, we sell our products directly to major domestic pharmaceutical retail chains enterprises, which then allocate these products to the affiliated retail outlets operated by them. We support our direct sales customers in the external promotion and display of our products and conduct regular training sessions for pharmacy sales staff. As of December 31, 2024, 2025 and March 31, 2026, the number of our direct sales customers amounted to 28, 27 and 19, respectively. We enter into standard framework agreements with our direct sales customers, and/or sales contracts on an annual basis. Pursuant to the direct sales agreements, we are responsible for the delivery of our products to our direct sales customers at our own cost. Generally, we do not allow product returns or exchanges except for defective products, which is subject to approval by our designated personnel. Our major direct sales customers are required to regularly confirm their inventory levels with us to avoid the sale of expired products. We typically grant our major direct sales customers a credit term of 30 to 90 days and direct sales customers typically pay us via wire transfer or bank acceptance bills.

Logistics Arrangement

We generally engage third-party logistics service providers to transport our products to our distributors and other direct customers. We have entered into logistics service agreements with these providers, pursuant to which they are responsible for furnishing comprehensive logistics services, encompassing storage, secondary packaging, and timely shipment to specified destinations. Our prerequisites mandate that such logistics service providers maintain contemporary pharmaceutical storage and distribution facilities. Moreover, they must hold third-party pharmaceutical logistics qualifications sanctioned by competent authorities. Pursuant to the logistics arrangements, these providers bear responsibility for any loss, damage, or contamination of transported drugs resulting from their negligence during the provision of logistics services. Breach of contract by the logistics providers, including failure to meet these obligations, may result in the imposition of liquidated damages.

PRICING

We formulate and implement a reasonable pricing strategy for our commercialized products. In determining our prices, we prioritize patient accessibility. We also take into account the applicable regulations and policies on the pharmaceutical industry, including medical insurance reimbursement standards and regulation of medical and pricing practices, as well as our R&D, production and marketing costs and expenses, the perceived value of products, our market share and the competitive landscape.

We are dedicated to closely monitoring new policies affecting the pricing of pharmaceuticals in China and formulating strategies to stay competitive and profitable.

Centralized Tender Process and Volume-based Procurement

The centralized tender process and volume-based procurement ("**VBP**") are two distinct but interrelated mechanisms in China's pharmaceutical procurement system, both aimed at reducing healthcare costs and increasing access to medications. The centralized tender process is a provincial or regional system used in China for public hospitals to purchase most medications at the bid prices. The procurement volume under centralized tender process is not guaranteed, and depends on hospital preferences and market demand. The VBP is a national or regional procurement mechanism that leverages large-volume government procurement to lower the prices of the selected medications. The VBP typically guarantees a large procurement volume, which encourages pharmaceutical companies to offer lower prices in exchange for assured sales. If a drug is included in VBP, its prices and sales volume to public hospitals will primarily be determined through the VBP scheme. Once a VBP cycle ends or for provinces not participating in VBP, such drugs can still be procured through the centralized tender process. If a drug does not win bids in VBP, it may still be procured through the centralized tender process, but it may experience a sharp decline in demand as public hospitals prioritize purchasing VBP-winning drugs. Out of the VBP scope, public hospitals primarily procure drugs at bid prices determined through the centralized tender process based on their needs.

Centralized Tender Process

The centralized tender process is held in different regions across China with varying terms and procedures. Generally, pharmaceutical companies bid to have their drugs listed on an online procurement platform operated at provincial or regional level, where public hospitals can choose to purchase the listed drug at the negotiated prices. We, as the pharmaceutical manufacturer and the holder of marketing authorizations for drugs covered by the centralized procurement program, submit bids in a centralized tender process to supply our applicable products to these institutions at specified prices. These bids are generally considered based on, among other things, price competitiveness, product quality, clinical effectiveness, as well as qualifications and reputation of the manufacturer. If we are successful in winning bids in a centralized tender process, the relevant products will be sold to the public medical institutions at the bid prices, which is the primary determinant of prices at which we sell our products to our distributors. The centralized tender process has created pricing pressure among substitute products.

We actively participate in the centralized tender process, carefully considering various factors, including the trade-off between price levels and sales volumes. The centralized tender process presents both challenges and opportunities for us. Challenges include potential declines in revenue and profit for products that do not win bids, loss of market share in regions where we fail to secure bids, and the pressure to adjust prices, which can affect profit margins. However, by leveraging our product differentiation bidding strategy, opportunities arise from cost and efficiency advantages from reduced selling and marketing expenses and expanded market access through successful bids. Our success in the centralized tender process relies on differentiating our products and pricing bids profitably, supported by national-level recognitions and quality evaluations.

VBP

Prices of certain pharmaceutical products in China sold to public hospitals and public medical institutions are affected by the VBP scheme. The VBP scheme aims to achieve a lower price of pharmaceuticals with mature, high-volume clinical usage and sufficient market competition through a competitive bidding process for large-volume procurement. The VBP scheme has rolled out at both national and regional levels.

The national VBP is a centralized procurement system to secure large volumes of essential drugs at significantly lower prices. Drugs selected for national VBP must have one originator and at least six manufactures of generic versions that pass consistency evaluation with the originator to ensure competition in the bidding process. Pharmaceutical companies compete to win bids by offering a substantial price reduction. By centralizing the procurement process, this mechanism also minimizes the role of distributors and intermediaries, improving efficiency and transparency of supply to public hospitals. As a result, the inclusion in the national schemes generally exerts substantial downward pricing pressure of the selected drugs. Its impact on the sales volume of a bid-winning drug depends on such drug's market share among its drug class prior to the implementation of such national schemes. Specifically, the national VBP scheme for pharmaceuticals imposes certain limitations on the number of provinces each winning bidder are entitled to supply. Therefore, pharmaceutical manufacturers which have a smaller market share prior to winning the VBP bid will usually experience a bump in sales volume. For pharmaceutical manufacturers which have a large market share, however, their sales volume may decrease after winning the bid in national VBP scheme for pharmaceuticals, as they have to share a smaller market with the other winning bidders. For drugs in the same drug class that are not included in such scheme (i.e. they do not win the bidding), they typically lose significant market share in public hospitals, while they are not mandatorily required to lower selling prices to align with the low-priced bid-winning drugs. A national VBP scheme typically lasts for a term ranging from one to three years.

Following the completion of national VBP schemes, continuation procurement often follows at provincial or regional level to stabilize the supply and pricing structure. If a drug was not previously included in the national schemes, it may participate in the continuation procurement. So far, the national government has never initiated a new round of national VBP after the drugs enter provincial continuation procurement stage. Besides, provincial governments also roll out VBP schemes at provincial or regional level to complement the national schemes. Similar to national VBP, the provincial VBPs exert downward pressure on drug price with a guaranteed procurement volume.

During the Track Record Period, a number of our products were subject to national or provincial VBP schemes. For example, Leweijing and Leiweitai participated in provincial VBP schemes and later in the national VBP scheme. In addition, Shuweijing, Tianze and Bailineng participated in provincial VBP schemes as of the Latest Practicable Date. For further details, see "— Our Portfolio Assets — Our Generics and Traditional Chinese Medicine Products." While the VBP scheme sometimes allows us to sell our products in larger volumes, it typically exerts downward pressure on the prices at which we sell our products to our distributors. To mitigate such impact, we continue to diversify our product portfolio by introducing new marketed drugs.

NRDL

The NRDL sets forth the payment standard for drugs under the basic medical insurance, work-related injury insurance and maternity insurance funds. The National Healthcare Security Administration of the PRC, together with other government authorities, have the power to determine the drugs included in the NRDL. As of March 31, 2026, certain of our generic drugs and traditional Chinese medicine products were included in the NRDL, including Leweijing, Leweitai, Tianze, Shuweijing, Bailineng, and astragalus granule. To achieve this, our products undergo a rigorous evaluation and approval procedure based on the NRDL's selection criteria. Being part of

the NRDL has substantial implications for our company as it determines the medical insurance reimbursement standards for our products. However, this may also lead to a decrease in the price of our products in certain provinces due to the transparent, multi-party negotiation mechanism for pricing. In addition, we are actively pursuing NRDL inclusion for iza-bren to enhance patient accessibility and broaden market reach. Iza-bren for the NPC indication has passed the eligibility review in the annual NRDL adjustment process, and we expect to participate in the NRDL price negotiation for this indication in the third quarter of 2026. We are also evaluating the potential inclusion of iza-bren in the Commercial Health Insurance Innovative Drug List as a supplementary payment channel.

NEDL

The NEDL aims at promoting essential drugs sold to patients at fair prices in the PRC and ensuring that the general public in the PRC has equal access to the essential drugs. The selection of drugs listed in the NEDL shall be in accordance with the principles of necessity for prevention and treatment, safety and effectiveness, reasonable price, easy to use and clinical preference. Propofol injectable emulsion and medium and long chain fat emulsion, covering two of our marketed products, were included in the 2018 NEDL. While it ensures that our products are deemed essential and are therefore more likely to be purchased even in times of economic downturn, this process can also exert downward pressure on our pricing strategy. The prices at which we can sell our products may decrease due to the fixed or maximum retail prices set by the NEDL.

Our pricing strategy and regulation are a delicate balance of participation in these four mechanisms. We strive to meet the criteria in each process, but we also must navigate the potential downward pressure on our pricing.

QUALITY CONTROL AND ASSURANCE

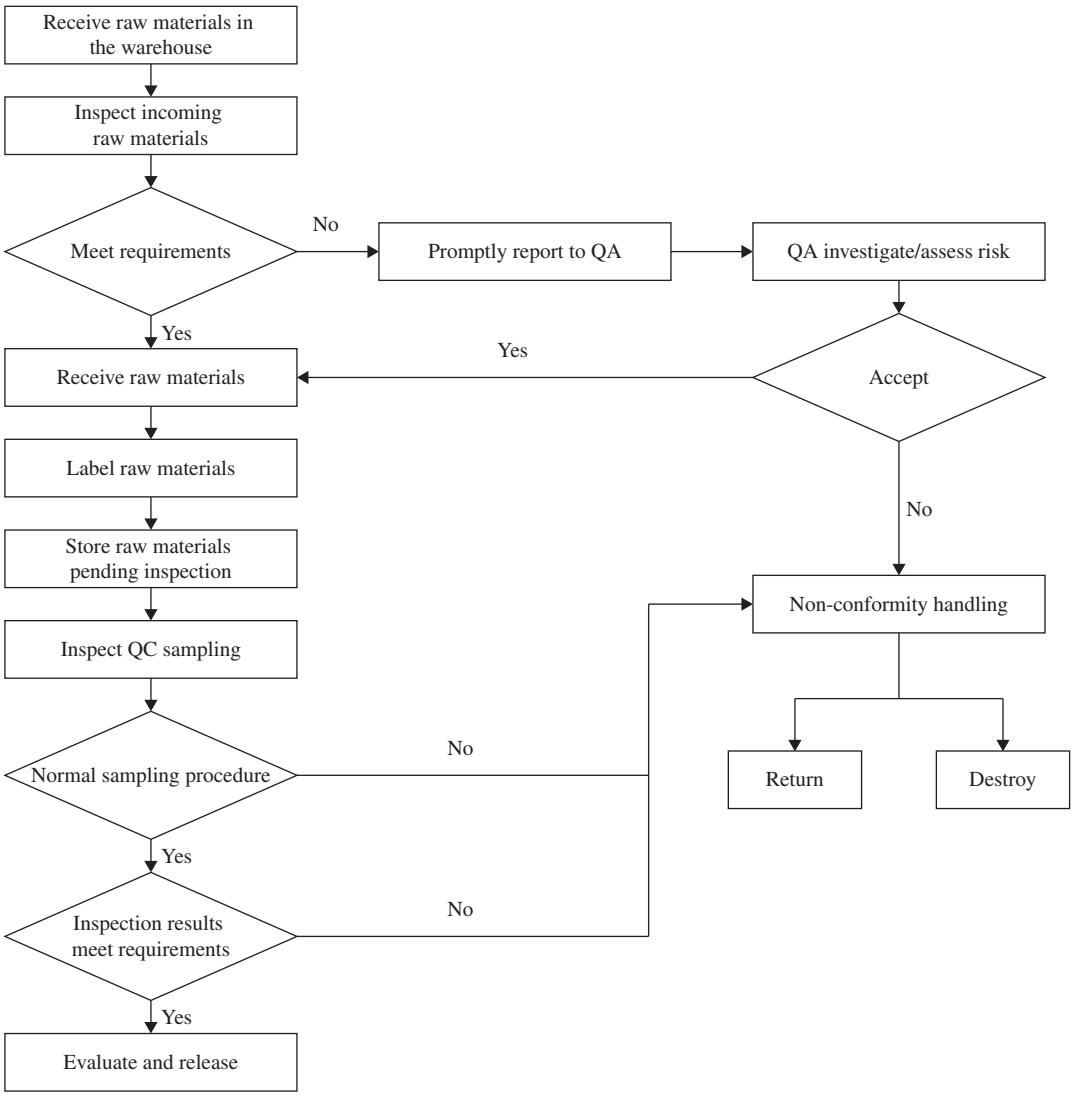
We have implemented comprehensive quality control procedures and protocols that span across the entire production lifecycle from raw material sourcing till the final products are delivered to customers. In strict compliance with the laws and regulations, including but not limited to, Pharmaceutical Administration Law of the People's Republic of China (《中華人民共和國藥品管理法》) and GMP for Medical Products Standards (《藥品生產質量管理規範》), we have established a comprehensive pharmaceutical quality management system. We have established an organizational structure including an independent quality management department that fulfills both Quality Assurance ("**QA**") and Quality Control ("**QC**") roles. Our Qualified Person ("**QP**") is responsible for independently ensuring that each batch of our pharmaceutical products meets all quality and regulatory standards before distribution. For details about our major licenses, permits and approvals, please see "— Licenses, Permits and Approvals."

Supply Chain Quality Control

We have adopted a comprehensive supplier management procedure. The QA department, in collaboration with relevant departments, conducts quality evaluations of all suppliers providing raw materials, including both on-site and off-site quality audits. Only suppliers who pass our evaluation are included in our approved supplier list. For details about our supply chain management, please see "— Manufacturing — Supply Chain Management."

Our QC personnel conducts sampling inspections of the materials procured in batches, and issues inspection reports indicating whether the materials meet quality standards within specified time limits. The QA personnel reviews these inspection reports alongside the material acceptance records and testing records to conduct a material audit assessment. Based on the assessment result, our quality management department head decides whether to approve the release of materials. We store the materials that are approved for release by category according to specified storage conditions and use such materials within their designated shelf lives.

The following flow chart illustrates our raw material quality control procedures:



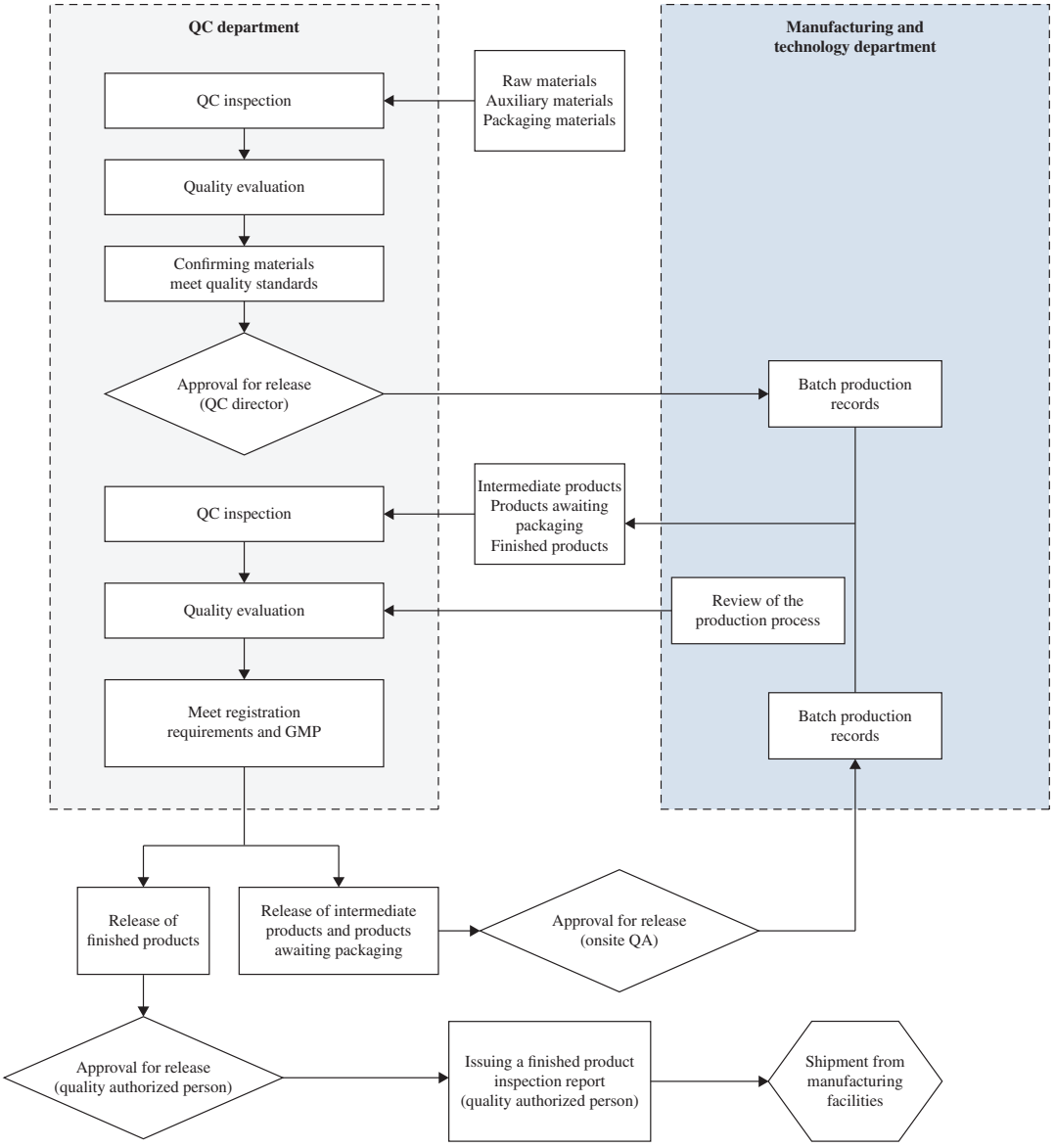
Manufacturing Quality Control

All of our manufacturing processes are conducted in accordance with our detailed production instructions, protocols and the GMP standards. Our QA personnel conduct rigorous quality monitoring at each stage of the production process. Upon completion of batch production, QC personnel collect and test samples, and the QA department conducts comprehensive audits evaluating inspection results, process compliance, deviation handling, and change management before issuing release or non-release notices.

Finished Product Quality Control

Upon completion of finished products in the production workshop, QC personnel collect and test samples and issue inspection reports. The QA department reviews batch production records, packaging records, and related deviation records to ensure each batch meets quality standards consistent with registration requirements and GMP. Only products accompanied by QA-issued certificates of compliance and release orders are released for shipment.

The following flow chart illustrates our quality control procedures for our in-process and final products:



After-sales Supervision

We have implemented a thorough management framework to oversee the quality and safety of our products in the post-marketing phase, including product complaints, product recalls, adverse drug reaction reporting, and monitoring. To this end, we have adopted a series of procedures, such as Product Complaint Handling Standard Operating Procedure, Recall Standard Operating Procedure, and Adverse Drug Reaction Reporting and Monitoring Standard Operating Procedure. We have staffed specialized personnel responsible for monitoring and reporting adverse drug reactions. These personnel systematically collect and meticulously record adverse reactions, regularly conduct drug safety risk assessments, and compile and submit safety update reports.

PRODUCT RETURNS

We have established a comprehensive internal control system to minimize the risks related to drug quality and safety to the greatest extent possible. During the Track Record Period and up to the Latest Practicable Date, we did not have any product recall due to quality issues.

We generally do not accept any product returns and exchanges, except for defective products, incorrect deliveries, damages, or policy-related factors. The primary responsibility for handling returns and exchanges lies with the respective business divisions, with support from the finance department, the quality control department and warehouses. Typically, the return process begins with a return request submitted by the business manager of the business division, and the business manager will coordinate the return with the distributors for the subsequent transportation to our warehouses after obtaining the approval of the head of that business division and our finance department. Upon arrival, our warehouse staff inspects the returned goods against the commercial delivery note, followed by a quality inspection and final review by the quality control department. For defective products, we are fully responsible for the cost of return and replacement of these products. For details of the return policy with our distributors, see "— Sales and Marketing — Sales — Distribution — Distributor Management." We have also implemented detailed procedures on how to handle quality complaints and provide for the contingency for any adverse patient reaction to our products. In addition, our sales and marketing team is responsible for following up customer complaints to ensure that they have been dealt with appropriately.

During the Track Record Period, when the product returns occurred and were accepted, the amount of actual product returns would offset the sales revenue. We estimated the future sales return of the products sold based on the historical experience and recorded refund liability for the expected returns, and simultaneously recognized an asset for the right to returned goods asset. As of December 31, 2024, 2025 and March 31, 2026, our refund liabilities amounted to RMB9.7 million, RMB7.6 million and RMB8.2 million, respectively; our right to returned goods assets amounted to RMB6.4 million, RMB4.8 million and RMB5.3 million, respectively. The cumulative amount of actual product return for the revenue recognized during the Track Record Period, as measured subsequent to the Track Record Period and up to June 30, 2026, was RMB7.2 million, accounting for 0.8% of the total revenue from the sales of pharmaceutical products, which was in line with the industry practice as advised by CIC. During the Track Record Period and up to the Latest Practicable Date, the amounts of our product returns and exchanges did not have a material adverse effect on our operations of business, and we had not experienced any material complaint or product liability or other legal claims from our customers due to problems associated with the quality of our products.

SUPPLIERS

During the Track Record Period, our suppliers primarily consisted of CROs and suppliers of raw materials, equipment, devices and construction services. We primarily procure our raw materials within the PRC, with a minor portion sourced from the United States. We select our suppliers by considering cost and their capability, quality, reputation, delivery and regulatory compliance.

Purchases from our five largest suppliers in each period during the Track Record Period were RMB217.2 million, RMB422.0 million and RMB105.9 million in 2024, 2025 and the three months ended March 31, 2026, respectively, representing 15.8%, 16.6% and 16.5% of our total purchases for the corresponding periods. Purchases from our largest supplier in 2024, 2025 and the three months ended March 31, 2026 were RMB73.2 million, RMB205.9 million and RMB37.2 million, respectively, representing 5.3%, 8.1% and 5.8% of our total purchases for the corresponding periods. Our suppliers generally provide us credit terms of 30 to 270 days, and we generally settle with them by bank transfer and bills. The following table sets forth details of our five largest suppliers for each year/period during the Track Record Period.

Suppliers	Background	Products/ Services Purchased	Commencement of Business Relationship	Purchase Amount	% of Total Purchase
				(RMB in thousands)	
For the year ended December 31, 2024					
Supplier A	A joint stock company established in 2010 and headquartered in Shanghai, primarily focusing on providing medical science technology consulting and development services, with a registered capital of RMB105.7 million	R&D services	2018	73,189	5.3
Supplier B	A U.S.-based leading global provider of advanced analytics, technology solutions, and clinical research services, ranking among the top 10 global CROs by revenue in 2025	R&D services	2023	46,161	3.3
Supplier C	A public hospital located in Guangzhou, Guangdong, with an initial capital of RMB260.2 million	R&D services	2019	37,256	2.7
Supplier D	A public hospital located in Shanghai, with an initial capital of RMB168.46 million	R&D services	2021	30,519	2.2
Supplier E	A limited liability company established in 2003 and headquartered in Shanghai, primarily focusing on pharmaceutical R&D services, including clinical trial management, regulatory consulting, and data management	R&D services	2023	30,036	2.2
Total				**217,161**	**15.8**
For the year ended December 31, 2025					
Supplier B	A U.S.-based leading global provider of advanced analytics, technology solutions, and clinical research services, ranking among the top 10 global CROs by revenue in 2025	R&D services	2023	205,869	8.1
Supplier F	A limited liability company established in 2006 and headquartered in Chengdu, Sichuan province, primarily focusing on providing human resources services and information resource services	Human resource management services	2021	92,373	3.6
Supplier D	A public hospital located in Shanghai, with an initial capital of RMB168.46 million	R&D services	2021	46,561	1.8
Supplier G	A joint stock company established in 1993 and headquartered in Shanghai, primarily focusing on providing pharmaceutical companies with process services and consumables, core equipment, and integrated engineering solutions. Supplier G is listed on the Shenzhen Stock Exchange, with a registered capital of RMB765.8 million	Equipment	2007	40,034	1.6
Supplier C	A public hospital located in Guangzhou, Guangdong, with an initial capital of RMB260.2 million	R&D services	2019	37,160	1.5
Total				**421,997**	**16.6**

Suppliers	Background	Products/ Services Purchased	Commencement of Business Relationship	Purchase Amount	% of Total Purchase
				(RMB in thousands)	
For the three months ended March 31, 2026					
Supplier F	A limited liability company established in 2006 and headquartered in Chengdu, Sichuan province, primarily focusing on providing human resources services and information resource services	Human resource management services	2021	37,157	5.8
Supplier H	A limited liability company established in 2017 and headquartered in Shenzhen, Guangdong province, primarily focusing on providing clinical trial drugs for biopharmaceutical enterprises	Drugs used in clinical trials	2023	20,002	3.1
Supplier B	A U.S.-based leading global provider of advanced analytics, technology solutions, and clinical research services, ranking among the top 10 global CROs by revenue in 2025	R&D services	2023	18,350	2.9
Supplier I	A limited liability company established in 2010 and headquartered in Taizhou, Jiangsu province, primarily focusing on mechanical and electrical equipment installation and building installation engineering	Engineering services	2025	15,817	2.5
Supplier J	A social organization established in Beijing in 2018, primarily dedicated to public science popularization and public welfare research related to public health	Marketing and promotion services	2025	14,614	2.3
Total				**105,940**	**16.5**

To the best of our knowledge, (i) all of our five largest suppliers for each year/period during the Track Record Period are independent third parties, and (ii) none of our Directors, their respective associates or any shareholder who owned more than 5% of our issued share capital as of the Latest Practicable Date has any interest in any of our five largest suppliers for each year/period during the Track Record Period.

CUSTOMERS

During the Track Record Period, our revenue was derived from license fee income and sales of pharmaceutical products. In 2024 and 2025, our revenue was primarily derived from license fee, while in the three months ended March 31, 2026, our revenue was primarily derived from sales of pharmaceutical products, mainly to third-party distributors. We sell a substantial portion of our products to third-party distributors in the PRC, who are our direct customers and are responsible for subsequently selling and delivering our products to hospitals, other medical institutions and pharmacies. We generally grant credit terms of 30 to 120 days to our major distributors, and they generally settle with us by bank transfer and bills.

Our revenue from our five largest customers in each period during the Track Record Period, calculated on the group level with entities controlled by the same group combined together, were RMB5,537.8 million, RMB2,306.9 million and RMB47.7 million in 2024, 2025 and the three months ended March 31, 2026, respectively, representing 95.1%, 91.5% and 50.7% of our total revenue for the corresponding periods. Our revenue from our largest customer in each period during the Track Record Period were RMB5,334.3 million, RMB2,136.9 million and RMB18.1 million, respectively, representing 91.6%, 84.8% and 19.2% of our total revenue for the corresponding

periods. For risks related to customer concentration, see "Risk Factors — Risks Relating to Our Reliance on Third Parties — We depend on a limited number of customers for a substantial portion of our revenue, and the loss of, or a significant reduction in sales to, one or more of our major customers would materially and adversely affect our business, result of operations and financial condition." The following table sets forth details of our five largest customers for each year/period during the Track Record Period.

Customers	Background	Products/ Services/ License Provided	Commencement of Business Relationship	Revenue Contribution	% of Total Revenue
				(RMB in thousands)	
For the year ended December 31, 2024					
BMS	A multinational pharmaceutical company headquartered in the U.S. BMS is a leading global pharmaceutical company with US$48.2 billion in revenue in 2025	Licensing of iza-bren	2023	5,334,291	91.6
Customer A	A joint stock company established in 2003 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals and medical devices. Customer A is listed on the Hong Kong Stock Exchange, with a registered capital of RMB3,120.7 million	Pharmaceutical products	2008	78,360	1.3
Customer B	A joint stock company established in 2007 and headquartered in Beijing, primarily focusing on sale of pharmaceuticals. Customer B is listed on the Hong Kong Stock Exchange, with a registered capital of RMB19,646.5 million	Pharmaceutical products	2011	70,112	1.2
Customer C	A joint stock company established in 1994 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals. Customer C is listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange, with a registered capital of RMB3,702.8 million	Pharmaceutical products	2010	28,777	0.5
Customer D	A state-owned enterprise established in 2000 and headquartered in Chongqing, primarily engaged in investment and management of chemical and pharmaceutical assets, with a registered capital of RMB4,041.5 million	Pharmaceutical products	2010	26,243	0.5
Total				**5,537,783**	**95.1**
For the year ended December 31, 2025					
BMS	A multinational pharmaceutical company headquartered in the U.S. BMS is a leading global pharmaceutical company with US$48.2 billion in revenue in 2025	Licensing of iza-bren	2023	2,136,918	84.8
Customer B	A joint stock company established in 2007 and headquartered in Beijing, primarily focusing on sale of pharmaceuticals. Customer B is listed on the Hong Kong Stock Exchange, with a registered capital of RMB19,646.5 million	Pharmaceutical products	2011	63,578	2.5
Customer A	A joint stock company established in 2003 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals and medical devices. Customer A is listed on the Hong Kong Stock Exchange, with a registered capital of RMB3,120.7 million	Pharmaceutical products	2008	62,821	2.5

Customers	Background	Products/ Services/ License Provided	Commencement of Business Relationship	Revenue Contribution	% of Total Revenue
				(RMB in thousands)	
Customer C	A joint stock company established in 1994 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals. Customer C is listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange, with a registered capital of RMB3,702.8 million	Pharmaceutical products	2010	22,786	0.9
Customer D	A state-owned enterprise established in 2000 and headquartered in Chongqing, primarily engaged in investment and management of chemical and pharmaceutical assets, with a registered capital of RMB4,041.5 million	Pharmaceutical products	2010	20,819	0.8
Total				**2,306,922**	**91.5**
For the three months ended March 31, 2026					
Customer A	A joint stock company established in 2003 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals and medical devices. Customer A is listed on the Hong Kong Stock Exchange, with a registered capital of RMB3,120.7 million	Pharmaceutical products	2008	18,064	19.2
Customer B	A joint stock company established in 2007 and headquartered in Beijing, primarily focusing on sale of pharmaceuticals. Customer B is listed on the Hong Kong Stock Exchange, with a registered capital of RMB19,646.5 million	Pharmaceutical products	2011	14,782	15.7
Customer C	A joint stock company established in 1994 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals. Customer C is listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange, with a registered capital of RMB3,702.8 million	Pharmaceutical products	2010	6,032	6.4
Customer D	A state-owned enterprise established in 2000 and headquartered in Chongqing, primarily engaged in investment and management of chemical and pharmaceutical assets, with a registered capital of RMB4,041.5 million	Pharmaceutical products	2010	5,297	5.6
Customer E	A joint stock company established in 1993 and headquartered in Kunming, Yunnan province, primarily focusing on sale of pharmaceuticals and medical devices. Customer E is listed on the Shenzhen Stock Exchange, with a registered capital of RMB1,784.3 million	Pharmaceutical products	2007	3,531	3.8
Total				**47,705**	**50.7**

To the best of our knowledge, (i) all of our five largest customers for each year/period during the Track Record Period are independent third parties, and (ii) none of our Directors, their respective associates or any shareholder who owned more than 5% of our issued share capital as of the Latest Practicable Date has any interest in any of our five largest customers for each year/period during the Track Record Period.

COMPETITION

We operate in a competitive industry, facing potential competition from many others working to develop therapies and products targeting the same indications and markets, such as multinational biopharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies. In our innovative biologics business, our drug candidates may, upon marketing approval, face competition from existing drugs and other drug candidates directed against the same molecular targets, mechanisms and indications, as an increasing number of biotechnology and multinational pharmaceutical companies commit substantial resources to our modalities of focus. In our generics and traditional Chinese medicine business, we face competition from other domestic manufacturers, including in the centralized tender process and the VBP scheme, where pricing pressure and competing bidders have affected, and may continue to affect, the sales volume, pricing and market share of such products. We believe that the primary competitive factors in our markets include the identification of promising targets, mechanisms, and pathways for drug development, molecule screening and design, efficacy and safety of drug candidates, manufacturing efficiency, and commercialization, as well as, for our generics and traditional Chinese medicine products, price competitiveness, product quality, clinical effectiveness, and manufacturer qualifications and reputation in centralized tender and VBP processes. We believe our continued success will depend on our following capabilities: the capability to develop innovative products and advanced technologies, including our proprietary HIRE-ADC, SEBA, GNC and HIRE-ARC platforms; the capability to apply technologies to all production lines; the capability to develop an extensive product portfolio spanning both our innovative biologics pipeline and our generics and traditional Chinese medicine business; the capability to maintain a highly efficient operational model; the capability to attract, retain and cultivate talent; the capability to maintain high quality standards; the capability to obtain and maintain regulatory approvals; and the capability to effectively market and promote products, including through our differentiated bidding strategy in centralized tender and VBP processes.

EMPLOYEES

As of March 31, 2026, we had a total of 3,271 full-time employees with 3,118 employees located in China and the rest in the U.S. The following table sets forth a breakdown of our employees by function as of March 31, 2026:

Function	Number	% of Total
R&D	1,702	52.0
Manufacturing	723	22.1
General and Administrative	697	21.3
Sales and Marketing	149	4.6
Total	**3,271**	**100.0**

We enter into standard labor, confidentiality and non-compete agreements with our employees. As of the Latest Practicable Date, our employees were represented by a labor union. We believe that we have maintained good working relationships with our employees. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material labor disputes or strikes that may have a material and adverse effect on our business, financial condition or results of operations.

We provide our employees with a diverse array of professional development opportunities and foster a performance-driven environment. We have a comprehensive talent development mechanism that nurtures employees from entry-level to expert proficiency. Every new employee undergoes comprehensive and systematic onboarding training tailored to their specific roles and responsibilities. We provide both internal and external training for our technical staff, which enables us to foster a diversified, multi-level, and well-structured talent pool. To motivate our R&D personnel to improve their work efficiency and expedite project progress while ensuring the quality of project deliverables, we have also implemented various measures such as Performance Management Measures and Invention and Innovation Reward Measures. These policies form a comprehensive talent incentive system that includes both short-term performance rewards and long-term career advancement opportunities.

We believe we offer our employees competitive compensation packages, reflecting our stakeholder-centric ethos which we believe leads to sustainable and durable growth. As required by PRC regulations, we participate in various government statutory employee benefit plans, including social insurance, namely pension insurance, medical insurance, unemployment insurance, work-related injury insurance, maternity insurance, and housing provident funds. Additionally, for certain of our employees in Chengdu, we provide supplementary insurance through the Chengdu Medicare (惠蓉保補充保險) to support their health and well-being. We also adhere to legal requirements by offering maternity leave, paternity leave, and other related benefits. We ensure a safe working environment that complies with safety standards, and we provide daily meal subsidies, transportation, and communication allowances. We have also enrolled each employee in the U.S. in the 401(K) retirement benefit plan, striving to ensure that every employee has financial security in their later years.

AWARDS AND RECOGNITION

Throughout our corporate history, we have received a number of major awards and accolades. The table sets forth a summary of the major awards and recognition we received as of the Latest Practicable Date:

Year(s) of Grant	Award/Recognition	Issuing Authority
2025	Sichuan Province All-Round Headquarters Enterprise (四川省全能型總部企業)	Sichuan Provincial Development and Reform Commission (四川省發展和改革委員會) among others
	Sichuan Provincial Specialized and New Small and Medium-Sized Enterprises (四川省專精特新中小企業)	Sichuan Provincial Economic and Information Department (四川省經濟和信息化廳)
	High-tech Enterprise (高新技術企業)	Science and Technology Department of Sichuan Province (四川省科學技術廳) among others
	Industry-leading Biotech Company (行業引領Biotech公司)	PharmCube (醫藥魔方)
	2025 Top 101 Chinese Pharmaceutical Industries (2025年中國製藥工業TOP101) and 2025 Top 101 Chinese Innovative Pharmaceutical Companies (2025中國創新藥企TOP101)	CMC-CHINA Pharmaceutical Industry Expo (CMC-CHINA 中國製藥工業博覽會) & Pharnex (藥融圈)
2024	Sichuan Provincial Specialized and New Small and Medium- Sized Enterprises (四川省專精特新中小企業)	Sichuan Provincial Economic and Information Department (四川省經濟和信息化廳)
	2024 China's Top 50 Most Innovative Companies (2024福布斯中國創新力企業50強)	Forbes

INTELLECTUAL PROPERTY

Our intellectual property rights are critical to our business, and we are committed to the development and protection of our intellectual properties.

We have a global portfolio of invention patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) 251 issued invention patents, including 83 in Chinese Mainland, 22 in the U.S., and 146 in other jurisdictions, and (ii) 938 patent applications, including 205 in Chinese Mainland, 77 in the U.S., 14 valid applications under the Patent Cooperation Treaty ("**PCT**") and 642 in other jurisdictions. As of the Latest Practicable Date, with respect to our Core Products, we owned 11 issued patents in Chinese Mainland, five issued patents in the U.S. and 32 issued patents in other jurisdictions, as well as 188 patent applications, including 26 in Chinese Mainland, 14 in the U.S., two valid applications under the PCT and 146 in other jurisdictions. The invention patents granted to, or under application by, us cover all material aspects of our Core Products.

The following table summarizes the details of the material issued patents and patent applications in connection with our Core products and innovative technology platforms. For further details, please see "Appendix VI — Statutory and General Information — B. Further Information about Our Business — 2. Our Material Intellectual Property Rights — (b) Patents."

Product	Scope of Patent Protection	Patent Number/ Application Number	Jurisdiction	Patent Holder/Applicant	Estimated Expiration Year*
Products on HIRE-ADC platform, including iza-bren and T-Bren	Antibody-Drug Conjugate Having Acidic Self-Stabilization Junction (一種帶酸性自穩定接頭的抗體-藥物偶聯物)	ZL201810620856.7	Chinese Mainland	Baili-Bio	June 2038
		12605458	U.S.	SystImmune	June 2038
		AU2018288029	Australia	SystImmune	June 2038
		JP7224365	Japan	SystImmune	June 2038
		US19263441	U.S.	SystImmune	N/A*
		EP18820589.2	EU	SystImmune	N/A*
	A Camptothecin Drug and Its Antibody Conjugate Thereof (一種喜樹鹼藥物及其抗體偶聯物)	AU2020442003	Australia	SystImmune	September 2040
		JP7780953	Japan	SystImmune	September 2040
		202010446142.6	Chinese Mainland	Baili-Bio	N/A*
		17601055	U.S.	SystImmune	N/A*
		20928032	EU	SystImmune	N/A*
		62022055331.2	Hong Kong	SystImmune	N/A*
		112022002353-7	Brazil	SystImmune	N/A*
	Camptothecin Drug Having High-Stability Hydrophilic Connecting Unit and Conjugate Thereof (一種帶有高穩定性親水連接單元的喜樹鹼類藥物及其偶聯物)	ZL202110610405.7	Chinese Mainland	Baili-Bio	June 2041
		JP7686677	Japan	SystImmune	May 2041
		18008798	U.S.	SystImmune	N/A*
		2021289927	Australia	SystImmune	N/A*
		21821872.5	EU	SystImmune	N/A*
		112022024930-6	Brazil	SystImmune	N/A*
	Linker-Drug Compounds and Methods of Making Thereof (一種連接子-藥物的製備方法)	202411139357.8	Chinese Mainland	Jingxi Pharmaceutical	N/A*
		19/512,057	U.S.	SystImmune	N/A*
		24855886.8	EU	SystImmune	N/A*
		2026-511985	Japan	SystImmune	N/A*
		2024326972	Australia	SystImmune	N/A*
		112026004119-6	Brazil	SystImmune	N/A*

Product	Scope of Patent Protection	Patent Number/ Application Number	Jurisdiction	Patent Holder/Applicant	Estimated Expiration Year*
	Bispecific Tetravalent Antibodies and Methods of Making and Using Thereof (雙特異性四價抗體及其製造和使用方法)	US10919977B2	U.S.	SystImmune	December 2035
		ZL201580036408.7	Chinese Mainland	Baili-Bio	December 2035
		EU3237005	EU	SystImmune	December 2035
		JP6947639	Japan	SystImmune	December 2035
		AU2015369831B2	Australia	SystImmune	December 2035
	Bispecific Antibody-camptothecin Drug Conjugate and Pharmaceutical Use thereof (雙特異性抗體-喜樹鹼類藥物偶聯物及其醫藥用途)	JP7767613	Japan	SystImmune	November 2042
		12577325	U.S.	SystImmune	November 2042
		202211425572.5	Chinese Mainland	Baili-Bio	N/A*
		22892173.0	EU	SystImmune	N/A*
		2022386505	Australia	SystImmune	N/A*
		1120240092313	Brazil	SystImmune	N/A*
Products on GNC platform	Multi-Specific Antibodies and Methods of Making and Using Thereof (多特異性抗體及其製備和使用方法)	US11787863	U.S.	SystImmune	March 2040
		ZL201880039401.4	Chinese Mainland	Baili-Bio	June 2038
		JP7399852	Japan	SystImmune	June 2038
		AU2018295118	Australia	SystImmune	June 2038
	Guidance and Navigation Control Proteins and Method of Making and Using Thereof (製導和導航控制蛋白及其製造和使用方法)	US 12,384,850 B2	U.S.	SystImmune	July 2038
		ZL201880039397.1	Chinese Mainland	Baili-Bio	June 2038
Products on SEBA platform	Anti-CD3 Antibodies and Methods of Making and Using Thereof (抗CD3抗體及其製備和使用方法)	US11535667	U.S.	SystImmune	September 2039
		CN110799538B	Chinese Mainland	Baili-Bio	June 2038
		ZL201880038306.2			
		16615109	U.S.	SystImmune	N/A*
	Bispecific Antibodies and Methods of Making and Using Thereof (雙特異性抗體及其製備和使用方法)	AU2018358138	Australia	SystImmune	June 2038
		ZL201880059130.9	Chinese Mainland	Baili-Bio	November 2038
		16760466	U.S.	SystImmune	N/A*

* Patent application.

As of the Latest Practicable Date, we had 361 registered trademarks in Chinese Mainland. We are also the registered owner of 23 domain names in Chinese Mainland. We have entered into license and collaboration arrangements with our business partners, through which we may grant access to our own intellectual property or gain access to the intellectual property of others.

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any proceedings in respect of our intellectual property rights, and we had not received notice of any claims of infringement of any intellectual property rights that may be threatened or pending in which we may be a claimant or a respondent.

In July, 2026, we engaged Beijing V&T (Chengdu) Law Firm, our legal adviser as to PRC intellectual property laws, to conduct certain freedom-to-operate searches and analyses ("**FTO Analysis**") in Chinese Mainland with respect to our Core Products. In addition, in July 2026, we engaged EpiMED LLC, our U.S. intellectual property counsel, to conduct certain freedom-to-operate searches and analyses with respect to our Core Products in the United States. Based on the conclusions of the FTO Analyses in both Chinese Mainland and the United States, we believe that we have the freedom to operate in connection with our Core Products without infringing any valid and enforceable patent rights of third parties, and did not identify any known blocking patents which would preclude us from proceeding with the planned activities related to our Core Products in both Chinese Mainland and the United States.

DATA PRIVACY AND PROTECTION

We have established procedures to protect the confidentiality of patients' data collected in our clinical trials. We maintain policies requiring our personnel to be trained on data protection, and require our CROs to have data protection clauses in our agreements with them. Personal information of patients enrolled in our clinical trials is processed solely in accordance with the informed consent form agreed upon by the patients. We have a number of ongoing or planned clinical studies in China and the U.S. For the purpose of the research and development of our innovative drug candidates, we provide online access of certain clinical data to SystImmune, our wholly-owned subsidiary in the U.S., and SystImmune transmitted certain clinical data to us. Any cross-border transmission of clinical trial data in connection with our product development efforts and regulatory communications is subject to the applicable local data and privacy protection laws, including those in China and the U.S. Together with our CROs and other collaboration partners, we have implemented controls and arrangements designed to ensure a data management and transfer plan is developed and implemented to govern the transfer of all clinical trial data. We have reported and completed filing for the clinical trial data of human genetic resources transmitted to our U.S. subsidiary and submitted information backup, according to the HGR Regulations. SystImmune's legal advisor as to U.S. laws, upon reviewing the facts presented, is of the view that, as of the Latest Practicable Date, the transfers of properly deidentified clinical data from and to SystImmune or its Chinese affiliates made in connection with its ongoing clinical operations with existing U.S. partners are not restricted by U.S. federal or state laws as applicable to SystImmune and its affiliates. We had not been subject to any claims, lawsuits, penalties or administrative actions relating to cross-border clinical data transfer activities as of the Latest Practicable Date.

During the Track Record Period and up to the Latest Practicable Date, to the best of our knowledge, we had not encountered any material data or personal information leakage. Our Directors confirm that we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with applicable laws and regulations for data privacy and protection as of the Latest Practicable Date.

PROPERTIES

We occupy certain properties in the PRC in connection with our business operations. According to section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all our interests in land or buildings, for the reason that, as of the date of the most recent audited combined balance sheet of our Group, none of the properties owned and leased by us had a carrying amount of 15% or more of our combined total assets.

Owned Properties

As of the Latest Practicable Date, we obtained 41 land use right certificates for properties with an aggregate site area of 242,332.91 sq.m. As of the Latest Practicable Date, we obtained 74 real estate ownership certificates for properties with total site area of approximately 131,366.44 sq.m. in the PRC. These parcels of properties mainly are located at Chengdu, Sichuan Province, and are primarily used as our production facilities, administrative offices and R&D buildings. Among all of our owned properties, nine land use rights with buildings on them were pledged to secure our bank borrowings.

As of the Latest Practicable Date, we had not obtained the real estate ownership certificates for two properties used for dormitories and warehouses, with an aggregate GFA of approximately 279.52 sq.m. (representing approximately 0.2% of the total GFAs of our owned properties). We acquired these properties through a judicial auction in November 2007.

As advised by our PRC Legal Advisor, properties without real estate ownership certificates are prohibited from being transferred and cannot be pledged pursuant to the Civil Code of the PRC (《中華人民共和國民法典》) and the Urban Real Estate Management Law of the PRC (《中華人民共和國城市房地產管理法》). In addition, should disputes arise due to title encumbrances to such properties or government action, we may encounter difficulties in continuing to use such properties and may be required to relocate. However, considering that these properties are primarily used for dormitories and warehouses, which are not directly related to our production and operations and only account for a small proportion of our owned properties, our Directors believe that (i) in the event that relocation becomes necessary, we will not incur significant time or cost to identify and relocate our operations to comparable alternative properties, and (ii) such identification and relocation would not have a material adverse impact on our business operations and financial condition. In addition, our Controlling Shareholder has committed to compensating us for any losses incurred in connection with these properties. Our Directors also confirm that, during the Track Record Period and up to the Latest Practicable Date, we had not received any notification from the government authorities requiring us to demolish and/or relocate from the properties with defective titles. Pursuant to the confirmations that we received from the relevant competent authorities and the credit report issued by Sichuan Provincial Big Data Center, during the Track Record Period, we had complied with other relevant laws and regulations with respect to real estate management in all material aspects and had not been subject to any penalties resulting from non-compliance of these laws and regulations. Based on the above and the public information, we believe, and our PRC Legal Advisor concur, that the title defects, either individually or collectively, will not have a material adverse impact on our business operations. See "Risk Factors — Other Risks Relating to Our Operations — Our legal right to certain properties may be challenged."

Leased Properties

As of the Latest Practicable Date, we leased 25 properties from third parties with an aggregate GFA of approximately 23,450.1 sq.m., which were primarily used as production facilities, warehouses and administrative offices. Our leases generally have a term ranging from one to five years. We will consider renewal of the leases upon their expiry.

Pursuant to the applicable PRC laws and regulations, both lessors and lessees must register lease agreements with the relevant authorities and obtain property leasing filing certificates. As of the Latest Practicable Date, eight of our lease agreements between us and third parties which are leased from third parties and used for production facilities, warehouses and administrative offices, with an aggregate GFA of approximately 6,596.6 sq.m., had not been registered with the relevant local authorities. As advised by our PRC Legal Advisor, failure to register an executed lease agreement will not affect its validity. However, we may be subject to a fine of no less than RMB1,000 and not exceeding RMB10,000 for each unregistered lease agreement if the relevant PRC governmental authorities require us to rectify it and we fail to do so within the prescribed time period. As of the Latest Practicable Date, we have not received any order from the relevant government authorities requiring us to register these lease agreements. We undertake to cooperate fully to facilitate the registration of lease agreements once we are notified of any requirements by the relevant government authorities. See "Risk Factors — Other Risks Relating to Our Operations — Our legal right to certain properties may be challenged."

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business to safeguard against risks and unexpected events in both China and U.S. Our insurance coverage comprises personnel-related policies such as pension, medical, work-related injury, maternity, and unemployment insurance. We have also secured comprehensive property insurance to cover losses arising from natural or other disasters affecting our manufacturing facilities or other assets. For each clinical trial, we have purchased clinical trial liability insurance to ensure comprehensive protection for the safety and legal rights of trial participants. Additionally, we have voluntarily purchased insurance to address safety concerns, including environmental pollution liability insurance for compensation in case of pollution incidents. We believe our existing insurance coverage is adequate for our present operations and in line with the industry practice in China and U.S.

LICENSES, PERMITS AND APPROVALS

We are subject to regular inspections, examinations and audits, and are required to maintain or renew the necessary permits, licenses and certifications for our business. During the Track Record Period and as of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from the relevant government authorities that are material for our business operations. We do not expect there to be any material legal impediment in renewing these licenses, permits, approvals and certificates as they expire in future as long as we are in compliance with applicable laws, regulations, and rules. The table below sets forth the relevant details of the material licenses, approvals and permits we hold for our operations.

License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
Drug Production License (藥品生產許可證) (川20160266)	Baili Pharmaceutical	Sichuan MPA	February 4, 2026	August 17, 2030
Drug Production License (藥品生產許可證) (川20160289)	Guorui Pharmaceutical	Sichuan MPA	September 3, 2025	September 2, 2030
Drug Production License (藥品生產許可證) (川20190504)	Jingxi Pharmaceutical	Sichuan MPA	June 23, 2026	January 24, 2029
Drug Production License (藥品生產許可證) (川20230590)	Baili-Bio	Sichuan MPA	October 21, 2025	March 27, 2028
Drug Production License (藥品生產許可證) (藏20240051)	Tianze Pharmaceutical	Xizang MPA	March 30, 2026	March 29, 2031
Drug Distribution License (藥品經營許可證) (川AA028a00425)	Our Company	Sichuan MPA	November 6, 2025	November 5, 2030
Drug Distribution License (藥品經營許可證) (藏AA891000042)	Lhasa Xinbo	Xizang MPA	March 4, 2024	March 3, 2029

During the Track Record Period, we possessed relevant export licenses for our R&D activities and business expansion plan in overseas market. Our subsidiaries, Baili Pharmaceutical, Guorui Pharmaceutical, and Baili-Bio maintain long-term Recordation of Customs Declaration Entities (海關報關單位備案), the registration dates of which are September 30, 2011, June 29, 2018, and March 10, 2020, respectively.

LEGAL PROCEEDINGS AND COMPLIANCE

We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. During the Track Record Period and as of the Latest Practicable Date, there was no litigation, arbitration or administrative proceedings pending or threatened against the Company or any of our Directors which could have a material and adverse effect on our financial condition or results of operations. We believe that, during the Track Record Period and up to the Latest Practicable Date, we had complied in all material respects with the applicable laws and regulations relating to our business operations. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business.

RISK MANAGEMENT AND INTERNAL CONTROLS

We are committed to developing and maintaining risk management and internal control systems comprised of policies and procedures tailored to our business operations. Our dedication lies in the continual enhancement of these systems to ensure their effectiveness.

Risk Management

We are exposed to various risks in our business operations, and we believe that risk management is important to our success. We have established our risk management systems to identify, assess, monitor and mitigate the risks that may hinder our success including strategic risks, operational risks, financial risks and legal risks.

To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [**REDACTED**], we have adopted or will continue to adopt risk management measures. These include establishing an Audit Committee to review and supervise our financial reporting process and internal control system, adopting various policies to ensure compliance with the Listing Rules covering risk management, connected transactions and information disclosure, providing anti-corruption and anti-bribery compliance training periodically to our senior management and employees, organizing training sessions for our Directors in respect of the requirements of the Listing Rules, enhancing our reporting and records system for production facilities, and establishing a set of emergency procedures for major quality-related issues.

Internal Controls

Our management team is responsible for establishing our internal control system and the audit committee of our Board is responsible for reviewing its effectiveness. We have engaged an independent internal control consultant to perform the internal review procedures in connection with the internal control of our Company and our major operating subsidiaries and to report factual findings on our Group's entity-level controls and internal controls of various processes, including financial reporting and disclosure controls, human resources and payroll management, general controls of IT system, taxation management, contract management, and other procedures of our operations. The internal control consultant performed the internal review procedures in May and June 2024, September 2025, as well as July 2026. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group's internal controls.

We are committed to establishing and maintaining risk management and internal control systems encompassing risks in R&D, procurement, production, sales, human resources, financial management, information systems and corporate governance. We continuously supervise and evaluate the effectiveness of these systems to ensure they are rectified and effectively controlled as our business develops.

Anti-bribery

We maintain a strict code of conduct and anti-corruption policies and strictly prohibit bribery or other improper payments in our business operations. This prohibition applies to all business activities, anywhere globally, whether involving government officials or healthcare professionals. We keep accurate books and records that reflect transactions and asset dispositions in reasonable detail. We will also ensure that future sales team personnel comply with applicable promotion and advertising requirements, including restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

Besides, our agreements with third-party promoters include anti-bribery clauses where both parties commit to opposing all forms of commercial bribery, which explicitly prohibit the use of money or other means in the name of any company, individuals, or their relatives to bribe medical institutions, healthcare professionals, regulatory agencies, or individuals (including their relatives) during the promotion of our products. All personnel involved in our marketing and promotional activities are prohibited from providing gifts or services for personal use to healthcare professionals or engaging in any activities intended to induce or reward prescription behaviours.

Non-Competition

We have instituted rigorous protocols to safeguard the proprietary information that arises during the development and production of our projects, which encompasses product formulations, preparation techniques, methodologies, and research strategies. The employment agreements between us and our senior management and key technical personnel include confidentiality clauses and non-compete agreements. In addition, researchers are strictly prohibited from removing electronic or physical records of experimental results and data from the laboratory premises. Through these meticulous steps, we diligently protect our intellectual property and maintain the integrity of our innovative endeavours.

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We recognize our responsibility to uphold high standards in health, safety, social and environmental practices. Following our [**REDACTED**], we are committed to complying with environmental, social, and governance ("**ESG**") reporting requirements. We have established an ESG work group to supervise our corporate social responsibility and measures for sustainable development. The ESG work group is responsible for (i) assessing and managing our ESG-related risks and opportunities, and deliberating on the formulation of, among others, our ESG strategic plans, management structure, systems, strategies and implementation rules so as to ensure the continuous execution and implementation of our ESG policies; (ii) making guidelines for and reviewing the identification and ranking of our important ESG issues; (iii) determining our key ESG issues; (iv) reviewing our ESG work and internal monitoring systems, and making recommendations on their appropriateness and effectiveness; (v) reviewing our ESG-related disclosure documents, including but not limited to the annual ESG reports; (vi) monitoring our ESG-related risks and making inquiries on and formulating corresponding measures for major issues that affect our performance of ESG-related work, and reviewing and supervising how such issues are handled; and (vii) providing ESG-related training and materials to the Board of Directors.

Governance on ESG Matters

The Board has collective responsibility for managing the impact of the material ESG risks and opportunities affecting the Group, formulating and establishing the Group's ESG-related mechanisms, policies and objectives, and reviewing the Group's performance against the ESG objectives on an annual basis and revising the ESG policy as appropriate if significant deviations from the objectives are identified.

We have established a three-tiered ESG management structure consisting of the Board, the ESG work group and the departments. The Board is informed through regular and ad hoc reports. Our ESG working group consists of 19 members, including our Director, senior management and department heads who will gain experience for monitoring ESG-related matters with the assistance of our independent ESG consultant.

Metrics and Targets on Environmental Matters

The Company strictly abides by the relevant national environmental protection laws and regulations in the production and operation, has established and strictly implemented the internal control system of environmental protection, and has increased investment in pollution control, constantly optimized the process and equipment, and reduce the pollution in the production process. We currently have five manufacturing facilities, housing a total of 29 production lines for our major approved drugs. Our Baili-Bio Base is dedicated to the production of innovative biologics, while our Guorui Base, Baili Base, Hiatt/Jingxi Base and Tianze Base are primarily used for the production of generic drugs and traditional Chinese medicine products. Consequently, our operations result in air pollution, wastewater, solid waste, or other hazardous wastes. To ensure compliance with national, industrial, and local environmental standards, laws, regulations, and policies, we have implemented internal policies for environmental risk prevention. These policies include: (i) strict adherence to GMP regulations and relevant pollutant emissions standards; (ii) conducting periodic environmental assessments on exhaust gas emissions, hazardous waste disposal, noise emissions, and wastewater emissions.

When setting targets for our ESG-related KPIs, we will carefully consider our historical consumption and discharge levels during the Track Record Period, along with our plans for future business expansion. Our approach aims to balance business growth with environmental protection to achieve sustainable development.

Pollutant Disposals

The waste we produce is divided into hazardous waste (such as chemical waste and liquid) and non-hazardous waste (such as waste from general office operations). In 2024, 2025 and the three months ended March 31, 2026, our solid hazardous waste discharge levels were approximately 1,868.7 tons, 1,387.5 tons and 353.2 tons, respectively. We mainly generated more solid hazardous waste in line with the growth of our research, development and manufacturing activities. To the extent feasible, we plan to further improve our operational efficiency to reduce the amount of solid waste generated from our operations.

Household garbage is collected and disposed of by sanitation services, while general packaging materials are sold externally. Hazardous waste is collected and entrusted to qualified third-party units for disposal. We have implemented the Hazardous Waste Management Policy to monitor the handling, use, storage, treatment and disposal of hazardous waste, including contractor management. We also implement continuous environmental monitoring and enforce strict incident response plans.

We have strengthened internal controls, including the implementation of the Environmental Protection Facilities Management System and Sewage Station Operation Procedures to standardize the operation of environmental protection facilities. Wastewater is treated at our self-built sewage treatment plant before discharge to the public sewage treatment plant for further treatment and compliant discharge. Waste liquids from quality testing are managed as hazardous waste and are collected and disposed of by qualified units.

Greenhouse Gases Emissions

Air pollution is treated at appropriate gas treatment facilities and then discharged in compliance with standards. We aim to reduce our greenhouse gases ("**GHG**") emissions and contribute to the transition to a low-carbon economy. Our greenhouse gas emissions primarily consist of Scope 1, Scope 2 and Scope 3 emissions. Scope 1 emissions mainly include the direct greenhouse gas emissions from our own R&D and other facilities. Scope 2 emissions primarily include the indirect greenhouse gas emissions from our usage of purchased electricity. Scope 3 emissions mainly consist of indirect emissions outside of Scope 2 emissions that occur in our value chain. Our Scope 1 emissions amounted to approximately 4,901.9 tonnes carbon dioxide equivalent ("**tCO_2e**"), 7,235.1 tCO_2e and 2,167.6 tCO_2e in 2024, 2025 and the three months ended March 31, 2026, respectively. Our Scope 2 emissions amounted to approximately 15,101.6 tCO_2e, 15,196.7 tCO_2e and 2,974.3 tCO_2e in 2024, 2025 and the three months ended March 31, 2026, respectively. Our Scope 3 emissions mainly consist of indirect emissions generated from freshwater and sewage treatment and business air travel amounted to approximately 960.2 tCO_2e, 732.5 tCO_2e and 173.2 tCO_2e in 2024, 2025 and the three months ended March 31, 2026, respectively.

We will implement measures in mitigating the GHG emissions, including (i) providing trainings and educate our employees on the concept of energy efficiency; (ii) posting water-saving or power-saving signs in eye-catching areas to cultivate our employees' awareness of environment protection; (iii) promoting paperless environment, encourage the usage of electronic copies instead of hard copies, the use of double-sided printing, and the use of single-sided printed paper when there is no confidential information on it; (iv) requiring employee to turn off all electrical appliances when they are not in use; and (v) implementing policies regarding waste management.

Resource Consumption

In pursuit of our sustainable development objectives, we rigorously oversee our environmental protection performance across various domains, including resource efficiency and energy consumption. We closely monitor our electricity and water consumption levels and actively implement strategies to enhance energy efficiency and promote water conservation. In aggregate, our electricity consumption levels were approximately 24.3 million kWh, 26.6 million kWh and 5.6 million kWh in 2024, 2025 and the three months ended March 31, 2026, respectively. Our water consumption levels amounted to approximately 728.5 thousand tons, 746.4 thousand tons and 167.7 thousand tons in 2024, 2025 and the three months ended March 31, 2026, respectively.

Climate Change

We believe that we are not susceptible to climate change. Moreover, we consider that potential changes to the regulations in the PRC regarding climate change will not adversely impact our business operations. We will continue to pay attention to risks regarding climate change and formulate emergency plans to safeguard us from climate change and extreme weather conditions, such as hurricane and rainstorms. As of the Latest Practicable Date, we had not experienced any material impact on our business operations or financial performance as a result of climate change or extreme weather conditions.

Targets

With the expansion of production and development of our business, we anticipate ongoing disposal needs and are committed to strictly managing pollutants. In 2024, we aimed to control (i) our pollutant disposals at approximately 118% of that recorded in 2023, (ii) our greenhouse gas (Scope 1 and 2) emissions at approximately 118% of that recorded in 2023, and (iii) resource consumption level at approximately 105% of that recorded in 2023. In 2025, we aimed to control (i) our pollutant disposals at approximately 105% of that recorded in 2023, (ii) our greenhouse gas (Scope 1 and 2) emissions at approximately 105% of that recorded in 2023, and (iii) resource consumption level at approximately 105% of that recorded in 2023. In 2026, we aim to control (i) our pollutant disposals at approximately 105% of that recorded in 2023, (ii) our greenhouse gas (Scope 1 and 2) emissions at approximately 105% of that recorded in 2023, and (iii) resource consumption level at approximately 105% of that recorded in 2023.

Work Safety

We are dedicated to ensuring a safe working environment for our employees. We firmly believe that a safe and healthy workplace is not only crucial for the well-being of our employees but also indispensable for the sustainability of our business. Our measures include pre-position training, annual safety training, regular emergency drills, provision of safety protection and emergency facilities, and labor protection supplies for all employees.

During the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents regarding occupational health and safety laws and regulations, and there had not been and were not any material safety issues, accidents and claims relating to our business operations.

Workplace Diversity

Within our company, we are steadfast in our commitment to fostering an open and inclusive workplace that champions equality. We adhere to a corporate policy of hiring employees based solely on their merits, offering equal opportunities regardless of gender, age, race, religion, or any other social or personal characteristics.